

## **Package leaflet: Information for the patient**

### **Amoxicillin 125mg/5ml & 250mg/5ml Oral Suspension BP**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their symptoms or their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Amoxicillin is and what it is used for
2. What you need to know before you take Amoxicillin
3. How to take Amoxicillin
4. Possible side effects
5. How to store Amoxicillin
6. Contents of the pack and other information

#### **1. WHAT AMOXICILLIN IS AND WHAT IT IS USED FOR**

Amoxicillin is one of a group of antibiotic medicines called penicillins. Amoxicillin works by interfering with the bacteria that cause the infection.

Amoxicillin can treat a wide range of infections including those of the following:

- chest (bronchitis or pneumonia)
- tonsils (tonsillitis)
- ears (otitis media)
- sinuses (sinusitis)
- kidneys
- heart (endocarditis)
- blood (septicaemia)
- the bladder or the urethra (the tube which carries urine from the bladder)
- the female reproductive system including infections associated with pregnancy and childbirth (puerperal sepsis and septic abortion)
- abdomen (intra-abdominal sepsis and peritonitis)
- skin, bone, teeth and gums (abscesses)
- gonorrhoea (a sexually transmitted infection)
- typhoid and paratyphoid (fevers caused by a group of bacteria called *Salmonella*)

Amoxicillin may also be used in combination with other medicines to treat stomach ulcers.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMOXICILLIN**

##### **Do not take Amoxicillin if**

- You are allergic to amoxicillin or any of the other ingredients of this medicine (listed in section 6)
- You have ever had a bad reaction or allergy to any penicillin-type antibiotic
- You have ever had a skin rash or swelling of the face or neck or shortness of breath when taking any antibiotic

## **Warnings and precautions**

Talk to your doctor or pharmacist before taking Amoxicillin if:

- You suffer from kidney problems, as you may require a lower dose than normal
- You are not passing urine regularly
- You have glandular fever, cytomegalovirus (CMV) infection or certain types of leukaemia - you may be at greater risk of developing a rash when you take this medicine
- You have an intolerance to some sugars or have diabetes mellitus, as this medicine contains sucrose.

## **Other medicines and Amoxicillin**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those not prescribed by a doctor. In particular tell your doctor if you are taking any of the following:

- 
- Anticoagulants e.g. warfarin, phenindione
- Chemotherapy drugs e.g. methotrexate
- Drugs used to treat gout (which can be caused by the build up of uric acid) e.g. probenecid, allopurinol, sulfinpyrazone
- Some other antibiotics (e.g. neomycin and tetracyclines can reduce the effect of amoxicillin)
- Oral typhoid vaccine (may not work if taken with amoxicillin)
- Some penicillins may increase the effects of muscle-relaxing drugs given as part of an anaesthetic for surgery. Tell the doctor you are taking amoxicillin if you need to have an anaesthetic.

## **Having urine or blood tests**

If you are having urine tests for diabetes (sugar in the urine) or blood tests for liver function let the doctor know. Amoxicillin can affect the results of these tests.

## **Pregnancy and breast-feeding**

Check with your doctor before you take this medicine if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

## **Amoxicillin Oral Suspension BP contains sucrose**

Amoxicillin 250mg/5ml Oral Suspension BP contains 2.72g of sucrose per 5ml, Amoxicillin 125mg/5ml Oral Suspension BP contains 2.68g of sucrose per 5ml.

- This should be taken into account in patients with diabetes mellitus.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. HOW TO TAKE AMOXICILLIN**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You may give/take amoxicillin before, with or after food. Space the doses as evenly as possible throughout the day. You should make sure you/your child have several more drinks of water each day unless told otherwise by your doctor.

## Dosage

**Note: One teaspoon is equivalent to 5 ml**

### Adults (including the elderly):

The maximum daily dose should not be more than 6g per day in total.

- The usual dose for most infections is 5ml of 250mg/5ml suspension to be taken 3 times a day.
- For more serious infections the dose may be doubled to 10ml of 250mg/5ml suspension 3 times a day.
- The following doses may be given in the following conditions:
  - Severe or recurrent chest infections: 3g twice daily
  - Simple urinary tract infections: two 3g doses with 10 to 12 hours between doses (short course)
  - Dental abscesses: two 3g doses with 8 hours between doses
  - Gonorrhoea: a single 3g dose
- For stomach ulcers, the following may be prescribed with other antibiotics:  
1 x 750 mg **or** 1 x 1 g twice a day for 7 days
- The following are the usual adult dosages for preventing infection during dental or other surgery:
  - If a general anaesthetic is not used, 3g one hour before surgery and another dose six hours later if necessary
  - If a general anaesthetic is used, 3g four hours before anaesthesia and 3g six hours after the initial dose

### Children:

- Children weighing more than 40kg should be given the usual adult dosage.
- Children weighing less than 40kg:
  - All doses are worked out depending on the child's body weight in kilograms. Your doctor will advise you how much medicine you should give to your baby or child. The usual dose is 40mg to 90mg for each kilogram of body weight a day, given in two or three divided doses.

### Patients with kidney problems

If you have kidney problems, the dose prescribed by your doctor may be lower than the usual dose.

### If you take more Amoxicillin than you should

If you (or somebody else) accidentally take too much of your medicine, speak to your doctor or pharmacist immediately. You should take this leaflet and any medicine you still have to show the doctor.

Severe cases of nausea, vomiting and diarrhoea can be treated with rehydration therapy, by drinking fluids containing sodium, water and sugar to prevent dehydration.

### If you forget to take Amoxicillin

If you forget to take a dose, take it as soon as you remember, unless it is within an hour of your next dose, then carry on as before. Do not take a double dose to make up for the dose you have missed.

### If you stop taking Amoxicillin

Keep taking this medicine until it is finished or your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, some bacteria may survive and cause the infection to come back, or your condition may re-occur or get worse.

If you/your child are still unwell after taking all the medicine, go and see your doctor. Never give/take more than the recommended dose each day.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

**Like all medicines, this medicine can cause side effects, although not everybody gets them.**

**If you experience any of the following events STOP taking your medicine, tell your doctor or go to your nearest hospital immediately:**

- Hypersensitivity or severe allergic reaction including swollen face or breathing problems.
- Severe diarrhoea with bleeding
- Allergic skin reactions with itching e.g. hives, nettle rash, blistering or peeling of the skin. If you start to itch or get a rash, STOP taking amoxicillin and tell your doctor immediately.
- Convulsions may occur in patients on high doses or with kidney problems
- Notice your urine becoming darker or your faeces becoming paler
- Notice your skin or the white of your eyes turning yellow (jaundice)
- Difficulty or discomfort in passing urine or having cloudy urine

**The following symptoms are less serious but you may wish to discuss them with your doctor or pharmacist if they become troublesome or last a long time.**

**Common side effects** (i.e. more than 1 in 100 people):

- Nausea (feeling sick) or diarrhoea

**Uncommon side effects** (i.e. between 1 in 100 and 1 in 1,000 people):

- Vomiting

**Very rare side effects** (i.e. less than 1 in 10,000 people):

- Thrush (a yeast infection of the vagina, mouth or skin folds). You can get treatment for thrush from your doctor or pharmacist.
- Tooth discolouration. The colour usually returns to normal with brushing.
- Blackening of the tongue
- Inflammation of the kidney
- Excessive body movements (hyperkinesia) or dizziness
- Reduction (reversible) in blood cell counts including anaemia (a reduction in the body's red blood cells or haemoglobin which may be characterised by feeling weak or light-headed) or a longer time taken for blood to clot.
- Crystalluria (forming of crystals in the urine)

**Not known:** frequency cannot be estimated from available data

- Meningitis (signs may include stiff neck, fever and vomiting)

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the yellow card scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. HOW TO STORE AMOXICILLIN

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date to be followed is that included by the pharmacist after the medicine is made up for you.

Protect from light.

Dry powder: Store in a dry place below 25°C.

Reconstituted suspension: Store for 7 days at 2°C-8°C in a refrigerator.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Amoxicillin Oral Suspension BP contains**

- The active ingredient is amoxicillin. Each 5ml spoonful of Amoxicillin 125mg/5ml or 250mg/5ml Oral Suspension BP contains either 125 mg or 250 mg of amoxicillin as amoxicillin trihydrate.
- The other ingredients are sodium benzoate (E211), disodium edetate, sodium citrate anhydrous, lemon flavour powder, quinoline yellow (E104) and sucrose.

### **What Amoxicillin Oral Suspension BP looks like and contents of the pack**

Amoxicillin 125mg/5ml and 250mg/5ml Oral Suspension BP is available as a pale yellow granular dry powder in a bottle for preparation of a yellow suspension with a lemon odour and flavour. When prepared by the pharmacist, the 125 mg/5 ml bottle contains 100 ml of suspension and the 250 mg/5 ml bottle contains 100 ml of suspension.

### **Marketing Authorisation Holder and Manufacturer**

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

### **The product is distributed by**

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

PL 06453/0021

PL 06453/0022

**This leaflet was last revised in January 2016.**

## **Package leaflet: Information for the patient**

### **Respillin 125mg/5ml & 250mg/5ml Oral Suspension BP** Amoxicillin

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their symptoms or their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

7. What Respillin is and what it is used for
8. What you need to know before you take Respillin
9. How to take Respillin
10. Possible side effects
11. How to store Respillin
12. Contents of the pack and other information

#### **1. WHAT RESPILLIN IS AND WHAT IT IS USED FOR**

Amoxicillin is one of a group of antibiotic medicines called penicillins. Amoxicillin works by interfering with the bacteria that cause the infection.

Amoxicillin can treat a wide range of infections including those of the following:

- chest (bronchitis or pneumonia)
- tonsils (tonsillitis)
- ears (otitis media)
- sinuses (sinusitis)
- kidneys
- heart (endocarditis)
- blood (septicaemia)
- the bladder or the urethra (the tube which carries urine from the bladder)
- the female reproductive system including infections associated with pregnancy and childbirth (puerperal sepsis and septic abortion)
- abdomen (intra-abdominal sepsis and peritonitis)
- skin, bone, teeth and gums (abscesses)
- gonorrhoea (a sexually transmitted infection)
- typhoid and paratyphoid (fevers caused by a group of bacteria called *Salmonella*)

Amoxicillin may also be used in combination with other medicines to treat stomach ulcers.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RESPILLIN**

##### **Do not take Respillin if**

- You are allergic to amoxicillin or any of the other ingredients of this medicine (listed in section 6)
- You have ever had a bad reaction or allergy to any penicillin-type antibiotic
- You have ever had a skin rash or swelling of the face or neck or shortness of breath when taking any antibiotic

## **Warnings and precautions**

Talk to your doctor or pharmacist before taking Respillin if:

- You suffer from kidney problems, as you may require a lower dose than normal
- You are not passing urine regularly
- You have glandular fever, cytomegalovirus (CMV) infection or certain types of leukaemia - you may be at greater risk of developing a rash when you take this medicine
- You have an intolerance to some sugars or have diabetes mellitus, as this medicine contains sucrose.

## **Other medicines and Respillin**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those not prescribed by a doctor. In particular tell your doctor if you are taking any of the following:

- 
- Anticoagulants e.g. warfarin, phenindione
- Chemotherapy drugs e.g. methotrexate
- Drugs used to treat gout (which can be caused by the build up of uric acid) e.g. probenecid, allopurinol, sulfinpyrazone
- Some other antibiotics (e.g. neomycin and tetracyclines can reduce the effect of amoxicillin)
- Oral typhoid vaccine (may not work if taken with amoxicillin)
- Some penicillins may increase the effects of muscle-relaxing drugs given as part of an anaesthetic for surgery. Tell the doctor you are taking amoxicillin if you need to have an anaesthetic.

## **Having urine or blood tests**

If you are having urine tests for diabetes (sugar in the urine) or blood tests for liver function let the doctor know. Amoxicillin can affect the results of these tests.

## **Pregnancy and breast-feeding**

Check with your doctor before you take this medicine if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

## **Respillin Oral Suspension BP contains sucrose**

Respillin 250mg/5ml Oral Suspension BP contains 2.72g of sucrose per 5ml, Respillin 125mg/5ml Oral Suspension BP contains 2.68g of sucrose per 5ml.

- This should be taken into account in patients with diabetes mellitus.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. HOW TO TAKE RESPILLIN**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You may give/take amoxicillin before, with or after food. Space the doses as evenly as possible throughout the day. You should make sure you/your child have several more drinks of water each day unless told otherwise by your doctor.

## Dosage

**Note: One teaspoon is equivalent to 5 ml**

### Adults (including the elderly):

The maximum daily dose should not be more than 6g per day in total.

- The usual dose for most infections is 5ml of 250mg/5ml suspension to be taken 3 times a day.
- For more serious infections the dose may be doubled to 10ml of 250mg/5ml suspension 3 times a day.
- The following doses may be given in the following conditions:
  - Severe or recurrent chest infections: 3g twice daily
  - Simple urinary tract infections: two 3g doses with 10 to 12 hours between doses (short course)
  - Dental abscesses: two 3g doses with 8 hours between doses
  - Gonorrhoea: a single 3g dose
- For stomach ulcers, the following may be prescribed with other antibiotics:  
1 x 750 mg **or** 1 x 1 g twice a day for 7 days
- The following are the usual adult dosages for preventing infection during dental or other surgery:
  - If a general anaesthetic is not used, 3g one hour before surgery and another dose six hours later if necessary
  - If a general anaesthetic is used, 3g four hours before anaesthesia and 3g six hours after the initial dose

### Children:

- Children weighing more than 40kg should be given the usual adult dosage.
- Children weighing less than 40kg:
  - All doses are worked out depending on the child's body weight in kilograms. Your doctor will advise you how much medicine you should give to your baby or child. The usual dose is 40mg to 90mg for each kilogram of body weight a day, given in two or three divided doses.

### Patients with kidney problems

If you have kidney problems, the dose prescribed by your doctor may be lower than the usual dose.

### If you take more Respillin than you should

If you (or somebody else) accidentally take too much of your medicine, speak to your doctor or pharmacist immediately. You should take this leaflet and any medicine you still have to show the doctor.

Severe cases of nausea, vomiting and diarrhoea can be treated with rehydration therapy, by drinking fluids containing sodium, water and sugar to prevent dehydration.

### If you forget to take Respillin

If you forget to take a dose, take it as soon as you remember, unless it is within an hour of your next dose, then carry on as before. Do not take a double dose to make up for the dose you have missed.

### If you stop taking Respillin

Keep taking this medicine until it is finished or your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, some bacteria may survive and cause the infection to come back, or your condition may re-occur or get worse.

If you/your child are still unwell after taking all the medicine, go and see your doctor. Never give/take more than the recommended dose each day.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

**Like all medicines, this medicine can cause side effects, although not everybody gets them.**

**If you experience any of the following events STOP taking your medicine, tell your doctor or go to your nearest hospital immediately:**

- Hypersensitivity or severe allergic reaction including swollen face or breathing problems.
- Severe diarrhoea with bleeding
- Allergic skin reactions with itching e.g. hives, nettle rash, blistering or peeling of the skin. If you start to itch or get a rash, STOP taking amoxicillin and tell your doctor immediately.
- Convulsions may occur in patients on high doses or with kidney problems
- Notice your urine becoming darker or your faeces becoming paler
- Notice your skin or the white of your eyes turning yellow (jaundice)
- Difficulty or discomfort in passing urine or having cloudy urine

**The following symptoms are less serious but you may wish to discuss them with your doctor or pharmacist if they become troublesome or last a long time.**

**Common side effects** (i.e. more than 1 in 100 people):

- Nausea (feeling sick) or diarrhoea

**Uncommon side effects** (i.e. between 1 in 100 and 1 in 1,000 people):

- Vomiting

**Very rare side effects** (i.e. less than 1 in 10,000 people):

- Thrush (a yeast infection of the vagina, mouth or skin folds). You can get treatment for thrush from your doctor or pharmacist.
- Tooth discolouration. The colour usually returns to normal with brushing.
- Blackening of the tongue
- Inflammation of the kidney
- Excessive body movements (hyperkinesia) or dizziness
- Reduction (reversible) in blood cell counts including anaemia (a reduction in the body's red blood cells or haemoglobin which may be characterised by feeling weak or light-headed) or a longer time taken for blood to clot.
- Crystalluria (forming of crystals in the urine)

**Not known:** frequency cannot be estimated from available data

- Meningitis (signs may include stiff neck, fever and vomiting)

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the yellow card scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. HOW TO STORE RESPILLIN

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date to be followed is that included by the pharmacist after the medicine is made up for you.

Protect from light.

Dry powder: Store in a dry place below 25°C.

Reconstituted suspension: Store for 7 days at 2°C-8°C in a refrigerator.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Respillin Oral Suspension BP contains**

- The active ingredient is amoxicillin. Each 5ml spoonful of Respillin 125mg/5ml or 250mg/5ml Oral Suspension BP contains either 125 mg or 250 mg of amoxicillin as amoxicillin trihydrate.
- The other ingredients are sodium benzoate (E211), disodium edetate, sodium citrate anhydrous, lemon flavour powder, quinoline yellow (E104) and sucrose.

### **What Respillin Oral Suspension BP looks like and contents of the pack**

Respillin 125mg/5ml and 250mg/5ml Oral Suspension BP is available as a pale yellow granular dry powder in a bottle for preparation of a yellow suspension with a lemon odour and flavour. When prepared by the pharmacist, the 125 mg/5 ml bottle contains 100 ml of suspension and the 250 mg/5 ml bottle contains 100 ml of suspension.

### **Marketing Authorisation Holder and Manufacturer**

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

### **The product is distributed by**

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

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**This leaflet was last revised in January 2016.**

## **NON-SYRINGE**

### **Package leaflet: Information for the patient**

#### **Amoxicillin 125mg/5ml & 250mg/5ml Oral Suspension Sugar Free BP**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their symptoms or their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Amoxicillin is and what it is used for
2. What you need to know before you take Amoxicillin
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5. How to store Amoxicillin
6. Contents of the pack and other information

### **1. WHAT AMOXICILLIN IS AND WHAT IT IS USED FOR**

Amoxicillin is one of a group of antibiotic medicines called penicillins. Amoxicillin works by interfering with the bacteria that cause the infection.

Amoxicillin can treat a wide range of infections including those of the following:

- chest (bronchitis or pneumonia)
- ears (otitis media)
- kidneys
- heart (endocarditis)
- the bladder or the urethra (the tube which carries urine from the bladder)
- the female reproductive system including infections caused by difficulties during childbirth (puerperal sepsis and septic abortion)
- abdomen (intra-abdominal sepsis and peritonitis)
- gonorrhoea (a sexually transmitted infection)
- infections associated with pregnancy
- typhoid and paratyphoid (fevers caused by a group of bacteria called *Salmonella*)
- tonsils (tonsillitis)
- sinuses (sinusitis)
- teeth
- blood (septicaemia)
- skin
- gums (abscesses)
- bone

Amoxicillin may also be used in combination with other medicines to treat stomach ulcers.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMOXICILLIN**

**Do not take Amoxicillin if:**

- You are allergic to amoxicillin or any of the other ingredients of this medicine (listed in section 6)
- You have ever had a bad reaction or allergy to any penicillin-type antibiotic
- You have ever had a skin rash or swelling of the face or neck or shortness of breath when taking any antibiotic

## **Warnings and precautions**

Talk to your doctor or pharmacist before taking Amoxicillin if:

- You suffer from kidney disease or kidney problems, as you may require a lower dose than normal
- You have glandular fever
- You are not passing water regularly
- You have an intolerance to some sugars as this medicine contains sorbitol

## **Other medicines and Amoxicillin**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those not prescribed by a doctor. In particular tell your doctor if you are taking any of the following:

- 
- Anticoagulants e.g. warfarin, phenindione
- Chemotherapy drugs e.g. methotrexate
- Drugs used to treat gout e.g. probenecid, allopurinol, sulfinpyrazone
- Some other antibiotics (e.g. neomycin and tetracyclines can reduce the effect of amoxicillin)
- Oral typhoid vaccine (may not work if taken with amoxicillin)
- Some penicillins may increase the effects of muscle-relaxing drugs given as part of an anaesthetic for surgery. Tell the doctor you are taking amoxicillin if you need to have an anaesthetic.

### Having urine or blood tests

If you or your child are having urine tests for diabetes (sugar in the urine) or blood tests for liver function, let the doctor know. Amoxicillin can affect the results of these tests.

## **Pregnancy and breast-feeding**

Check with your doctor before you take this medicine if you are pregnant or breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

## **Amoxicillin Oral Suspension Sugar Free BP contains sorbitol**

This medicinal product contains sorbitol. Sorbitol may cause stomach upset and diarrhoea. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. HOW TO TAKE AMOXICILLIN**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Try to give/take this medicine as part of the daily routine, for example at mealtimes. You may give/take amoxicillin before, with or after food, unless the label advises a specific time. You should make sure you/your child have several more drinks of water each day unless told otherwise by your doctor.

### **Dosage:**

#### **Adults (including the elderly):**

The total daily dose should not exceed 6 g in total, given in divided doses.

- The usual dose for most infections is 5 ml of 250 mg/5 ml suspension to be taken 3 times a day.

- For more serious infections the dose may be doubled to 10 ml of 250 mg/5 ml suspension 3 times a day.
- The following doses may be given in the following conditions:
  - Severe or recurrent chest infections: 3 g twice daily
  - Simple urinary tract infections: two 3 g doses with 10 to 12 hours between doses (short course)
  - Dental abscesses: two 3 g doses given orally with 8 hours between doses
  - Gonorrhoea: a single 3 g dose
- For stomach ulcers, the following may be prescribed with other antibiotics: 1 x 750 mg **or** 1 x 1 g twice a day for 7 days
- The following are the usual adult dosages for preventing infection during dental or other surgery:
  - If a general anaesthetic is not used, 3 g given orally one hour before surgery and another dose six hours later if necessary
  - If a general anaesthetic is used, 3 g given orally four hours before anaesthesia and 3 g six hours after the initial dose

#### **Children:**

- Children weighing more than 40 kg should be given the usual adult dosage.
- Children weighing less than 40 kg:
  - All doses are worked out depending on the child's body weight in kilograms. Your doctor will advise you how much medicine you should give to your baby or child. The usual dose is 40 mg to 90 mg for each kilogram of body weight a day, given in two or three divided doses.

#### **Patients with kidney problems**

If you have kidney problems, the dose prescribed by your doctor may be lower than the usual dose.

#### **If you take more Amoxicillin than you should**

If you (or somebody else) accidentally take too much of your medicine, speak to your doctor or go to your nearest hospital immediately. You should take this leaflet and any medicine you still have to show the doctor.

Severe cases of nausea, vomiting and diarrhoea can be treated with rehydration therapy, by drinking fluids containing sodium, water and sugar to prevent dehydration.

#### **If you forget to take Amoxicillin**

If you forget to take a dose, take it as soon as you remember, unless it is within an hour of your next dose, then carry on as before. Do not take a double dose to make up for the dose you have missed.

#### **If you stop taking Amoxicillin**

Keep taking this medicine until it is finished or your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, some bacteria may survive and cause the infection to come back, or your condition may re-occur or get worse.

If you/your child, are still unwell after taking all the medicine, go and see your doctor. Never give/take more than the recommended dose each day.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you or your child experience any of the following events STOP taking your medicine and tell your doctor or go to your nearest hospital immediately:**

- Hypersensitivity – symptoms may include swollen face, mouth, lips, throat or tongue, reddening of the skin, breathing problems, joint pain and fever. If these symptoms occur, STOP taking amoxicillin right away and tell your doctor.
- Severe diarrhoea possibly with bleeding
- Allergic skin reactions with itching e.g. hives, nettle rash, blistering or peeling of the skin. If you start to itch or get a rash, STOP taking amoxicillin and tell your doctor immediately.
- Convulsions may occur in patients on high doses or with kidney problems
- Darker coloured urine, faeces becoming paler
- Yellowing of the skin or the whites of your eyes (jaundice)
- Difficulty or discomfort in passing urine or having blood in the urine

**The following events are less serious but you may wish to discuss them with your doctor or pharmacist if they become troublesome or last a long time.**

**Common side effects** (have been reported in more than 1 in 100 people) include:

- Nausea (feeling sick) or diarrhoea

**Uncommon side effects** (have been reported in between 1 in 100 and 1 in 1000 people taking amoxicillin) include:

- Vomiting

**Very rare side effects** (have been reported in less than 1 in 10,000 people) include:

- Thrush (a yeast infection of the vagina, mouth or skin folds). You can get treatment for thrush from your doctor or pharmacist.
- Tooth discolouration. The colour usually returns to normal with brushing.
- Blackening of the tongue
- Inflammation of the kidney
- Excessive body movements (hyperkinesia) or dizziness
- Reduction (reversible) in blood cell counts which may cause anaemia (may be characterised by feeling weak or light-headed) or a longer time taken for blood to clot. Tell your doctor that you are taking amoxicillin if you are having blood tests.
- Crystalluria, forming of crystals in the urine

**Not known:** frequency cannot be estimated from available data

- Meningitis (signs may include stiff neck, fever and vomiting)

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the yellow card scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE AMOXICILLIN**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date to be followed is that included by the pharmacist after the medicine is made up for you.

Store in original package. Keep the bottle tightly closed.

Dry powder: Store in a dry place below 25°C.

Reconstituted suspension: Store up to 14 days at 2°C-8°C in a refrigerator.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Amoxicillin Oral Suspension Sugar Free BP contains**

- The active ingredient is amoxicillin. Amoxicillin Oral Suspension Sugar Free BP is available in two strengths containing either 125 mg/5 ml or 250 mg/5 ml of amoxicillin as amoxicillin trihydrate.
- The other ingredients are sodium benzoate (E211), disodium edetate, sodium citrate, orange bramble flavour, quinoline yellow (E104), citric acid monohydrate, colloidal anhydrous silica, xanthan gum, sorbitol (E420) and saccharin sodium.

### **What Amoxicillin Oral Suspension Sugar Free BP looks like and contents of the pack**

The suspensions are pale yellow with a characteristic odour.

Amoxicillin Oral Suspensions Sugar Free BP are available in bottles of 100ml.

### **Marketing Authorisation Holder and Manufacturer**

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

### **The product is distributed by: \*\***

PL 06453/0049 Amoxicillin 125mg/5ml Oral Suspension Sugar Free BP

PL 06453/0050 Amoxicillin 250mg/5ml Oral Suspension Sugar Free BP

### **This leaflet was last revised in December 2015 .**

\*\*This product is distributed by the following OLS:

Kent Pharmaceuticals Limited, Repton Road Measham, DE12 7DT, U.K. – hospital & retail

Actavis, Barnstaple, EX32 8NS, UK – retail only

Teva U.K. Limited, Eastbourne, BN22 9AG – retail only

Almus Pharmaceuticals, 43 Cox Lane, Chessington, KT9 1SN, UK- retail only

## **SYRINGE**

### **Package leaflet: Information for the patient**

#### **Amoxicillin 125mg/5ml & 250mg/5ml Oral Suspension Sugar Free BP**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their symptoms or their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Amoxicillin is and what it is used for
2. What you need to know before you take Amoxicillin
3. How to take Amoxicillin
4. Possible side effects
5. How to store Amoxicillin
6. Contents of the pack and other information

### **1. WHAT AMOXICILLIN IS AND WHAT IT IS USED FOR**

Amoxicillin is one of a group of antibiotic medicines called penicillins. Amoxicillin works by interfering with the bacteria that cause the infection.

Amoxicillin can treat a wide range of infections including those of the following:

- chest (bronchitis or pneumonia)
- ears (otitis media)
- kidneys
- heart (endocarditis)
- the bladder or the urethra (the tube which carries urine from the bladder)
- the female reproductive system including infections caused by difficulties during childbirth (puerperal sepsis and septic abortion)
- abdomen (intra-abdominal sepsis and peritonitis)
- gonorrhoea (a sexually transmitted infection)
- infections associated with pregnancy
- typhoid and paratyphoid (fevers caused by a group of bacteria called *Salmonella*)
- tonsils (tonsillitis)
- sinuses (sinusitis)
- teeth
- blood (septicaemia)
- skin
- gums (abscesses)
- bone

Amoxicillin may also be used in combination with other medicines to treat stomach ulcers.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMOXICILLIN**

#### **Do not take Amoxicillin if:**

- You are allergic to amoxicillin or any of the other ingredients of this medicine (listed in section 6)
- You have ever had a bad reaction or allergy to any penicillin-type antibiotic
- You have ever had a skin rash or swelling of the face or neck or shortness of breath when taking any antibiotic

## Warnings and precautions

Talk to your doctor or pharmacist before taking Amoxicillin if:

- You suffer from kidney disease or kidney problems, as you may require a lower dose than normal
- You have glandular fever
- You are not passing water regularly
- You have an intolerance to some sugars as this medicine contains sorbitol

## Other medicines and Amoxicillin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those not prescribed by a doctor. In particular tell your doctor if you are taking any of the following:

- 
- Anticoagulants e.g. warfarin, phenindione
- Chemotherapy drugs e.g. methotrexate
- Drugs used to treat gout e.g. probenecid, allopurinol, sulfinpyrazone
- Some other antibiotics (e.g. neomycin and tetracyclines can reduce the effect of amoxicillin)
- Oral typhoid vaccine (may not work if taken with amoxicillin)
- Some penicillins may increase the effects of muscle-relaxing drugs given as part of an anaesthetic for surgery. Tell the doctor you are taking amoxicillin if you need to have an anaesthetic.

### Having urine or blood tests

If you or your child are having urine tests for diabetes (sugar in the urine) or blood tests for liver function, let the doctor know. Amoxicillin can affect the results of these tests.

## Pregnancy and breast-feeding

Check with your doctor before you take this medicine if you are pregnant or breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

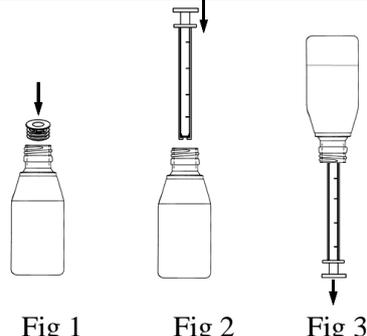
## Amoxicillin Oral Suspension Sugar Free BP contains sorbitol

This medicinal product contains sorbitol. Sorbitol may cause stomach upset and diarrhoea.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## 3. HOW TO TAKE AMOXICILLIN

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

TO THE PHARMACIST: INSTRUCTIONS FOR RECONSTITUTION OF THE POWDER	
<ol style="list-style-type: none"><li>1. Remove the cap and add the correct volume of potable water (84 ml for the 125 mg/5 ml and 82 ml for the 250 mg/5 ml strength of product)</li><li>2. Replace the cap and shake until all powder is dispersed.</li><li>3. Remove the cap once more and place the adaptor (Fig 1) into the bottle opening. The adaptor should not be removed at any stage.</li><li>4. Replace the cap, do not shake any further.</li></ol>	 <p>The diagram illustrates the three steps of reconstitution. Fig 1 shows a bottle with its cap being removed. Fig 2 shows a syringe adding water to the bottle. Fig 3 shows an adaptor being inserted into the bottle's opening.</p>

## TO THE PATIENT: INSTRUCTIONS FOR USE OF THE SYRINGE

1. Remove the cap and if necessary push the adaptor into the neck of the bottle (Fig 1).
2. Push the plunger of the syringe to remove all the air.
3. Insert the syringe into the adaptor until it is firmly in place (Fig 2).
4. While holding the bottle and syringe shake the contents gently.
5. While holding the bottle, turn the entire assembly upside down.
6. While supporting the syringe draw off the required amount of medicine into the syringe (Fig 3).
7. Turn the assembly back up the right way and remove the syringe from the bottle.
8. Replace the cap onto the bottle.

Administer the dose by introducing the tip of the syringe into the mouth of the infant/child, then apply a light pressure on the plunger to slowly release the solution. Keep it out of the reach of children.

Note: For subsequent dosage follow steps 3 and 4 above, before shaking in order to prevent leakage.

Try to give/take this medicine as part of the daily routine, for example at mealtimes. You may give/take amoxicillin before, with or after food, unless the label advises a specific time. You should make sure you/your child have several more drinks of water each day unless told otherwise by your doctor.

### **Dosage:**

#### **Adults (including the elderly):**

The total daily dose should not exceed 6 g in total, given in divided doses.

- The usual dose for most infections is 5 ml of 250 mg/5 ml suspension to be taken 3 times a day.
- For more serious infections the dose may be doubled to 10 ml of 250 mg/5 ml suspension 3 times a day.
- The following doses may be given in the following conditions:
  - Severe or recurrent chest infections: 3 g twice daily
  - Simple urinary tract infections: two 3 g doses with 10 to 12 hours between doses (short course)
  - Dental abscesses: two 3 g doses given orally with 8 hours between doses
  - Gonorrhoea: a single 3 g dose
- For stomach ulcers, the following may be prescribed with other antibiotics:  
1 x 750 mg **or** 1 x 1 g twice a day for 7 days
- The following are the usual adult dosages for preventing infection during dental or other surgery:
  - If a general anaesthetic is not used, 3 g given orally one hour before surgery and another dose six hours later if necessary
  - If a general anaesthetic is used, 3 g given orally four hours before anaesthesia and 3 g six hours after the initial dose

#### **Children:**

- Children weighing more than 40 kg should be given the usual adult dosage.
- Children weighing less than 40 kg:
  - All doses are worked out depending on the child's body weight in kilograms. Your doctor will advise you how much medicine you should give to your baby or child. The usual dose is 40 mg to 90 mg for each kilogram of body weight a day, given in two or three divided doses.

#### **Patients with kidney problems**

If you have kidney problems, the dose prescribed by your doctor may be lower than the usual dose.

### **If you take more Amoxicillin than you should**

If you (or somebody else) accidentally take too much of your medicine, speak to your doctor or go to your nearest hospital immediately. You should take this leaflet and any medicine you still have to show the doctor.

Severe cases of nausea, vomiting and diarrhoea can be treated with rehydration therapy, by drinking fluids containing sodium, water and sugar to prevent dehydration.

### **If you forget to take Amoxicillin**

If you forget to take a dose, take it as soon as you remember, unless it is within an hour of your next dose, then carry on as before. Do not take a double dose to make up for the dose you have missed.

### **If you stop taking Amoxicillin**

Keep taking this medicine until it is finished or your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, some bacteria may survive and cause the infection to come back, or your condition may re-occur or get worse.

If you/your child, are still unwell after taking all the medicine, go and see your doctor. Never give/take more than the recommended dose each day.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you or your child experience any of the following events STOP taking your medicine and tell your doctor or go to your nearest hospital immediately:**

- Hypersensitivity – symptoms may include swollen face, mouth, lips, throat or tongue, reddening of the skin, breathing problems, joint pain and fever. If these symptoms occur, STOP taking amoxicillin right away and tell your doctor.
- Severe diarrhoea possibly with bleeding
- Allergic skin reactions with itching e.g. hives, nettle rash, blistering or peeling of the skin. If you start to itch or get a rash, STOP taking amoxicillin and tell your doctor immediately.
- Convulsions may occur in patients on high doses or with kidney problems
- Darker coloured urine, faeces becoming paler
- Yellowing of the skin or the whites of your eyes (jaundice)
- Difficulty or discomfort in passing urine or having blood in the urine

**The following events are less serious but you may wish to discuss them with your doctor or pharmacist if they become troublesome or last a long time.**

**Common side effects** (have been reported in more than 1 in 100 people) include:

- Nausea (feeling sick) or diarrhoea

**Uncommon side effects** (have been reported in between 1 in 100 and 1 in 1000 people taking amoxicillin) include:

- Vomiting

**Very rare side effects** (have been reported in less than 1 in 10,000 people) include:

- Thrush (a yeast infection of the vagina, mouth or skin folds). You can get treatment for thrush from your doctor or pharmacist.
- Tooth discolouration. The colour usually returns to normal with brushing.
- Blackening of the tongue

- Inflammation of the kidney
- Excessive body movements (hyperkinesia) or dizziness
- Reduction (reversible) in blood cell counts which may cause anaemia (may be characterised by feeling weak or light-headed) or a longer time taken for blood to clot. Tell your doctor that you are taking amoxicillin if you are having blood tests.
- Crystalluria, forming of crystals in the urine

**Not known:** frequency cannot be estimated from available data

- Meningitis (signs may include stiff neck, fever and vomiting)

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the yellow card scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE AMOXICILLIN**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date to be followed is that included by the pharmacist after the medicine is made up for you.

Store in original package. Keep the bottle tightly closed.

Dry powder: Store in a dry place below 25°C.

Reconstituted suspension: Store up to 14 days at 2°C-8°C in a refrigerator.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Amoxicillin Oral Suspension Sugar Free BP contains**

- The active ingredient is amoxicillin. Amoxicillin Oral Suspension Sugar Free BP is available in two strengths containing either 125 mg/5 ml or 250 mg/5 ml of amoxicillin as amoxicillin trihydrate.
- The other ingredients are sodium benzoate (E211), disodium edetate, sodium citrate, orange bramble flavour, quinoline yellow (E104), citric acid monohydrate, colloidal anhydrous silica, xanthan gum, sorbitol (E420) and saccharin sodium.

### **What Amoxicillin Oral Suspension Sugar Free BP looks like and contents of the pack**

The suspensions are pale yellow with a characteristic odour.

Amoxicillin Oral Suspensions Sugar Free BP are available in bottles of 100ml.

### **Marketing Authorisation Holder and Manufacturer**

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

**The product is distributed by: \*\***

PL 06453/0049 Amoxicillin 125mg/5ml Oral Suspension Sugar Free BP

PL 06453/0050 Amoxicillin 250mg/5ml Oral Suspension Sugar Free BP

**This leaflet was last revised in December 2015**

\*\*This product is distributed by the following OLS:

Kent Pharmaceuticals Limited, Repton Road Measham, DE12 7DT, U.K. – hospital & retail  
Actavis, Barnstaple, EX32 8NS, UK – retail only  
Teva U.K. Limited, Eastbourne, BN22 9AG – retail only

## **NON-SYRINGE**

### **Package leaflet: Information for the patient**

#### **Respillin 125mg/5ml & 250mg/5ml Oral Suspension Sugar Free BP**

Amoxicillin

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their symptoms or their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Respillin is and what it is used for
2. What you need to know before you take Respillin
1. How to take Respillin
2. Possible side effects
3. How to store Respillin
4. Contents of the pack and other information

### **1. WHAT RESPILLIN IS AND WHAT IT IS USED FOR**

Amoxicillin is one of a group of antibiotic medicines called penicillins. Amoxicillin works by interfering with the bacteria that cause the infection.

Amoxicillin can treat a wide range of infections including those of the following:

- chest (bronchitis or pneumonia)
- ears (otitis media)
- kidneys
- heart (endocarditis)
- the bladder or the urethra (the tube which carries urine from the bladder)
- the female reproductive system including infections caused by difficulties during childbirth (puerperal sepsis and septic abortion)
- abdomen (intra-abdominal sepsis and peritonitis)
- gonorrhoea (a sexually transmitted infection)
- infections associated with pregnancy
- typhoid and paratyphoid (fevers caused by a group of bacteria called *Salmonella*)
- tonsils (tonsillitis)
- sinuses (sinusitis)
- teeth
- blood (septicaemia)
- skin
- gums (abscesses)
- bone

Amoxicillin may also be used in combination with other medicines to treat stomach ulcers.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RESPILLIN**

**Do not take Respillin if:**

- You are allergic to amoxicillin or any of the other ingredients of this medicine (listed in section 6)
- You have ever had a bad reaction or allergy to any penicillin-type antibiotic
- You have ever had a skin rash or swelling of the face or neck or shortness of breath when taking any antibiotic

## Warnings and precautions

Talk to your doctor or pharmacist before taking Respillin if:

- You suffer from kidney disease or kidney problems, as you may require a lower dose than normal
- You have glandular fever
- You are not passing water regularly
- You have an intolerance to some sugars as this medicine contains sorbitol

## Other medicines and Respillin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those not prescribed by a doctor. In particular tell your doctor if you are taking any of the following:

- 
- Anticoagulants e.g. warfarin, phenindione
- Chemotherapy drugs e.g. methotrexate
- Drugs used to treat gout e.g. probenecid, allopurinol, sulfinpyrazone
- Some other antibiotics (e.g. neomycin and tetracyclines can reduce the effect of amoxicillin)
- Oral typhoid vaccine (may not work if taken with amoxicillin)
- Some penicillins may increase the effects of muscle-relaxing drugs given as part of an anaesthetic for surgery. Tell the doctor you are taking amoxicillin if you need to have an anaesthetic.

### Having urine or blood tests

If you or your child are having urine tests for diabetes (sugar in the urine) or blood tests for liver function, let the doctor know. Amoxicillin can affect the results of these tests.

## Pregnancy and breast-feeding

Check with your doctor before you take this medicine if you are pregnant or breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

## Respillin Oral Suspension Sugar Free BP contains sorbitol

This medicinal product contains sorbitol. Sorbitol may cause stomach upset and diarrhoea.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## 3. HOW TO TAKE RESPILLIN

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Try to give/take this medicine as part of the daily routine, for example at mealtimes. You may give/take amoxicillin before, with or after food, unless the label advises a specific time.

You should make sure you/your child have several more drinks of water each day unless told otherwise by your doctor.

### Dosage:

#### Adults (including the elderly):

The total daily dose should not exceed 6 g in total, given in divided doses.

- The usual dose for most infections is 5 ml of 250 mg/5 ml suspension to be taken 3 times a day.

- For more serious infections the dose may be doubled to 10 ml of 250 mg/5 ml suspension 3 times a day.
- The following doses may be given in the following conditions:
  - Severe or recurrent chest infections: 3 g twice daily
  - Simple urinary tract infections: two 3 g doses with 10 to 12 hours between doses (short course)
  - Dental abscesses: two 3 g doses given orally with 8 hours between doses
  - Gonorrhoea: a single 3 g dose
- For stomach ulcers, the following may be prescribed with other antibiotics: 1 x 750 mg **or** 1 x 1 g twice a day for 7 days
- The following are the usual adult dosages for preventing infection during dental or other surgery:
  - If a general anaesthetic is not used, 3 g given orally one hour before surgery and another dose six hours later if necessary
  - If a general anaesthetic is used, 3 g given orally four hours before anaesthesia and 3 g six hours after the initial dose

#### **Children:**

- Children weighing more than 40 kg should be given the usual adult dosage.
- Children weighing less than 40 kg:
  - All doses are worked out depending on the child's body weight in kilograms. Your doctor will advise you how much medicine you should give to your baby or child. The usual dose is 40 mg to 90 mg for each kilogram of body weight a day, given in two or three divided doses.

#### **Patients with kidney problems**

If you have kidney problems, the dose prescribed by your doctor may be lower than the usual dose.

#### **If you take more Respillin than you should**

If you (or somebody else) accidentally take too much of your medicine, speak to your doctor or go to your nearest hospital immediately. You should take this leaflet and any medicine you still have to show the doctor.

Severe cases of nausea, vomiting and diarrhoea can be treated with rehydration therapy, by drinking fluids containing sodium, water and sugar to prevent dehydration.

#### **If you forget to take Respillin**

If you forget to take a dose, take it as soon as you remember, unless it is within an hour of your next dose, then carry on as before. Do not take a double dose to make up for the dose you have missed.

#### **If you stop taking Respillin**

Keep taking this medicine until it is finished or your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, some bacteria may survive and cause the infection to come back, or your condition may re-occur or get worse.

If you/your child, are still unwell after taking all the medicine, go and see your doctor. Never give/take more than the recommended dose each day.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you or your child experience any of the following events STOP taking your medicine and tell your doctor or go to your nearest hospital immediately:**

- Hypersensitivity – symptoms may include swollen face, mouth, lips, throat or tongue, reddening of the skin, breathing problems, joint pain and fever. If these symptoms occur, STOP taking amoxicillin right away and tell your doctor.
- Severe diarrhoea possibly with bleeding
- Allergic skin reactions with itching e.g. hives, nettle rash, blistering or peeling of the skin. If you start to itch or get a rash, STOP taking amoxicillin and tell your doctor immediately.
- Convulsions may occur in patients on high doses or with kidney problems
- Darker coloured urine, faeces becoming paler
- Yellowing of the skin or the whites of your eyes (jaundice)
- Difficulty or discomfort in passing urine or having blood in the urine

**The following events are less serious but you may wish to discuss them with your doctor or pharmacist if they become troublesome or last a long time.**

**Common side effects** (have been reported in more than 1 in 100 people) include:

- Nausea (feeling sick) or diarrhoea

**Uncommon side effects** (have been reported in between 1 in 100 and 1 in 1000 people taking amoxicillin) include:

- Vomiting

**Very rare side effects** (have been reported in less than 1 in 10,000 people) include:

- Thrush (a yeast infection of the vagina, mouth or skin folds). You can get treatment for thrush from your doctor or pharmacist.
- Tooth discolouration. The colour usually returns to normal with brushing.
- Blackening of the tongue
- Inflammation of the kidney
- Excessive body movements (hyperkinesia) or dizziness
- Reduction (reversible) in blood cell counts which may cause anaemia (may be characterised by feeling weak or light-headed) or a longer time taken for blood to clot. Tell your doctor that you are taking amoxicillin if you are having blood tests.
- Crystalluria, forming of crystals in the urine

**Not known:** frequency cannot be estimated from available data

- Meningitis (signs may include stiff neck, fever and vomiting)

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the yellow card scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. HOW TO STORE RESPILLIN

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date to be followed is that included by the pharmacist after the medicine is made up for you.

Store in original package. Keep the bottle tightly closed.

Dry powder: Store in a dry place below 25°C.

Reconstituted suspension: Store up to 14 days at 2°C-8°C in a refrigerator.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Respillin Oral Suspension Sugar Free BP contains**

- The active ingredient is amoxicillin. Respillin Oral Suspension Sugar Free BP is available in two strengths containing either 125 mg/5 ml or 250 mg/5 ml of amoxicillin as amoxicillin trihydrate.
- The other ingredients are sodium benzoate (E211), disodium edetate, sodium citrate, orange bramble flavour, quinoline yellow (E104), citric acid monohydrate, colloidal anhydrous silica, xanthan gum, sorbitol (E420) and saccharin sodium.

### **What Respillin Oral Suspension Sugar Free BP looks like and contents of the pack**

The suspensions are pale yellow with a characteristic odour.  
Respillin Oral Suspensions Sugar Free BP are available in bottles of 100ml.

### **Marketing Authorisation Holder and Manufacturer**

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

### **The product is distributed by: \*\***

PL 06453/0049 Respillin 125mg/5ml Oral Suspension Sugar Free BP  
PL 06453/0050 Respillin 250mg/5ml Oral Suspension Sugar Free BP

### **This leaflet was last revised in December 2015 .**

\*\*This product is distributed by the following OLS:

Kent Pharmaceuticals Limited, Repton Road Measham, DE12 7DT, U.K. – hospital & retail

Actavis, Barnstaple, EX32 8NS, UK – retail only

Teva U.K. Limited, Eastbourne, BN22 9AG – retail only

Almus Pharmaceuticals, 43 Cox Lane, Chessington, KT9 1SN, UK- retail only

## **SYRINGE**

### **Package leaflet: Information for the patient**

#### **Respillin 125mg/5ml & 250mg/5ml Oral Suspension Sugar Free BP**

Amoxicillin

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their symptoms or their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Respillin is and what it is used for
2. What you need to know before you take Respillin
3. How to take Respillin
4. Possible side effects
5. How to store Respillin
6. Contents of the pack and other information

### **1. WHAT RESPILLIN IS AND WHAT IT IS USED FOR**

Amoxicillin is one of a group of antibiotic medicines called penicillins. Amoxicillin works by interfering with the bacteria that cause the infection.

Amoxicillin can treat a wide range of infections including those of the following:

- chest (bronchitis or pneumonia)
- ears (otitis media)
- kidneys
- heart (endocarditis)
- the bladder or the urethra (the tube which carries urine from the bladder)
- the female reproductive system including infections caused by difficulties during childbirth (puerperal sepsis and septic abortion)
- abdomen (intra-abdominal sepsis and peritonitis)
- gonorrhoea (a sexually transmitted infection)
- infections associated with pregnancy
- typhoid and paratyphoid (fevers caused by a group of bacteria called *Salmonella*)
- tonsils (tonsillitis)
- sinuses (sinusitis)
- teeth
- blood (septicaemia)
- skin
- gums (abscesses)
- bone

Amoxicillin may also be used in combination with other medicines to treat stomach ulcers.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RESPILLIN**

**Do not take Respillin if:**

- You are allergic to amoxicillin or any of the other ingredients of this medicine (listed in section 6)
- You have ever had a bad reaction or allergy to any penicillin-type antibiotic
- You have ever had a skin rash or swelling of the face or neck or shortness of breath when taking any antibiotic

## Warnings and precautions

Talk to your doctor or pharmacist before taking Respillin if:

- You suffer from kidney disease or kidney problems, as you may require a lower dose than normal
- You have glandular fever
- You are not passing water regularly
- You have an intolerance to some sugars as this medicine contains sorbitol

## Other medicines and Respillin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those not prescribed by a doctor. In particular tell your doctor if you are taking any of the following:

- 
- Anticoagulants e.g. warfarin, phenindione
- Chemotherapy drugs e.g. methotrexate
- Drugs used to treat gout e.g. probenecid, allopurinol, sulfinpyrazone
- Some other antibiotics (e.g. neomycin and tetracyclines can reduce the effect of amoxicillin)
- Oral typhoid vaccine (may not work if taken with amoxicillin)
- Some penicillins may increase the effects of muscle-relaxing drugs given as part of an anaesthetic for surgery. Tell the doctor you are taking amoxicillin if you need to have an anaesthetic.

### Having urine or blood tests

If you or your child are having urine tests for diabetes (sugar in the urine) or blood tests for liver function, let the doctor know. Amoxicillin can affect the results of these tests.

## Pregnancy and breast-feeding

Check with your doctor before you take this medicine if you are pregnant or breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

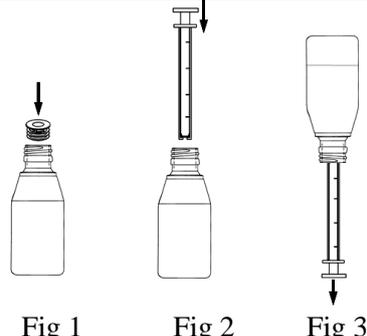
## Respillin Oral Suspension Sugar Free BP contains sorbitol

This medicinal product contains sorbitol. Sorbitol may cause stomach upset and diarrhoea.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## 3. HOW TO TAKE RESPILLIN

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

TO THE PHARMACIST: INSTRUCTIONS FOR RECONSTITUTION OF THE POWDER	
1. Remove the cap and add the correct volume of potable water (84 ml for the 125 mg/5 ml and 82 ml for the 250 mg/5 ml strength of product)	
2. Replace the cap and shake until all powder is dispersed.	
3. Remove the cap once more and place the adaptor (Fig 1) into the bottle opening. The adaptor should not be removed at any stage.	
4. Replace the cap, do not shake any further.	

## TO THE PATIENT: INSTRUCTIONS FOR USE OF THE SYRINGE

1. Remove the cap and if necessary push the adaptor into the neck of the bottle (Fig 1).
2. Push the plunger of the syringe to remove all the air.
3. Insert the syringe into the adaptor until it is firmly in place (Fig 2).
4. While holding the bottle and syringe shake the contents gently.
5. While holding the bottle, turn the entire assembly upside down.
6. While supporting the syringe draw off the required amount of medicine into the syringe (Fig 3).
7. Turn the assembly back up the right way and remove the syringe from the bottle.
8. Replace the cap onto the bottle.

Administer the dose by introducing the tip of the syringe into the mouth of the infant/child, then apply a light pressure on the plunger to slowly release the solution. Keep it out of the reach of children.

Note: For subsequent dosage follow steps 3 and 4 above, before shaking in order to prevent leakage.

Try to give/take this medicine as part of the daily routine, for example at mealtimes. You may give/take amoxicillin before, with or after food, unless the label advises a specific time. You should make sure you/your child have several more drinks of water each day unless told otherwise by your doctor.

### **Dosage:**

#### **Adults (including the elderly):**

The total daily dose should not exceed 6 g in total, given in divided doses.

- The usual dose for most infections is 5 ml of 250 mg/5 ml suspension to be taken 3 times a day.
- For more serious infections the dose may be doubled to 10 ml of 250 mg/5 ml suspension 3 times a day.
- The following doses may be given in the following conditions:
  - Severe or recurrent chest infections: 3 g twice daily
  - Simple urinary tract infections: two 3 g doses with 10 to 12 hours between doses (short course)
  - Dental abscesses: two 3 g doses given orally with 8 hours between doses
  - Gonorrhoea: a single 3 g dose
- For stomach ulcers, the following may be prescribed with other antibiotics:  
1 x 750 mg **or** 1 x 1 g twice a day for 7 days
- The following are the usual adult dosages for preventing infection during dental or other surgery:
  - If a general anaesthetic is not used, 3 g given orally one hour before surgery and another dose six hours later if necessary
  - If a general anaesthetic is used, 3 g given orally four hours before anaesthesia and 3 g six hours after the initial dose

#### **Children:**

- Children weighing more than 40 kg should be given the usual adult dosage.
- Children weighing less than 40 kg:
  - All doses are worked out depending on the child's body weight in kilograms. Your doctor will advise you how much medicine you should give to your baby or child. The usual dose is 40 mg to 90 mg for each kilogram of body weight a day, given in two or three divided doses.

#### **Patients with kidney problems**

If you have kidney problems, the dose prescribed by your doctor may be lower than the usual dose.

### **If you take more Respillin than you should**

If you (or somebody else) accidentally take too much of your medicine, speak to your doctor or go to your nearest hospital immediately. You should take this leaflet and any medicine you still have to show the doctor.

Severe cases of nausea, vomiting and diarrhoea can be treated with rehydration therapy, by drinking fluids containing sodium, water and sugar to prevent dehydration.

### **If you forget to take Respillin**

If you forget to take a dose, take it as soon as you remember, unless it is within an hour of your next dose, then carry on as before. Do not take a double dose to make up for the dose you have missed.

### **If you stop taking Respillin**

Keep taking this medicine until it is finished or your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, some bacteria may survive and cause the infection to come back, or your condition may re-occur or get worse.

If you/your child, are still unwell after taking all the medicine, go and see your doctor. Never give/take more than the recommended dose each day.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you or your child experience any of the following events STOP taking your medicine and tell your doctor or go to your nearest hospital immediately:**

- Hypersensitivity – symptoms may include swollen face, mouth, lips, throat or tongue, reddening of the skin, breathing problems, joint pain and fever. If these symptoms occur, STOP taking amoxicillin right away and tell your doctor.
- Severe diarrhoea possibly with bleeding
- Allergic skin reactions with itching e.g. hives, nettle rash, blistering or peeling of the skin. If you start to itch or get a rash, STOP taking amoxicillin and tell your doctor immediately.
- Convulsions may occur in patients on high doses or with kidney problems
- Darker coloured urine, faeces becoming paler
- Yellowing of the skin or the whites of your eyes (jaundice)
- Difficulty or discomfort in passing urine or having blood in the urine

**The following events are less serious but you may wish to discuss them with your doctor or pharmacist if they become troublesome or last a long time.**

**Common side effects** (have been reported in more than 1 in 100 people) include:

- Nausea (feeling sick) or diarrhoea

**Uncommon side effects** (have been reported in between 1 in 100 and 1 in 1000 people taking amoxicillin) include:

- Vomiting

**Very rare side effects** (have been reported in less than 1 in 10,000 people) include:

- Thrush (a yeast infection of the vagina, mouth or skin folds). You can get treatment for thrush from your doctor or pharmacist.
- Tooth discolouration. The colour usually returns to normal with brushing.
- Blackening of the tongue

- Inflammation of the kidney
- Excessive body movements (hyperkinesia) or dizziness
- Reduction (reversible) in blood cell counts which may cause anaemia (may be characterised by feeling weak or light-headed) or a longer time taken for blood to clot. Tell your doctor that you are taking amoxicillin if you are having blood tests.
- Crystalluria, forming of crystals in the urine

**Not known:** frequency cannot be estimated from available data

- Meningitis (signs may include stiff neck, fever and vomiting)

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the yellow card scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE RESPILLIN**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date to be followed is that included by the pharmacist after the medicine is made up for you.

Store in original package. Keep the bottle tightly closed.

Dry powder: Store in a dry place below 25°C.

Reconstituted suspension: Store up to 14 days at 2°C-8°C in a refrigerator.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Respillin Oral Suspension Sugar Free BP contains**

- The active ingredient is amoxicillin. Respillin Oral Suspension Sugar Free BP is available in two strengths containing either 125 mg/5 ml or 250 mg/5 ml of amoxicillin as amoxicillin trihydrate.
- The other ingredients are sodium benzoate (E211), disodium edetate, sodium citrate, orange bramble flavour, quinoline yellow (E104), citric acid monohydrate, colloidal anhydrous silica, xanthan gum, sorbitol (E420) and saccharin sodium.

### **What Respillin Oral Suspension Sugar Free BP looks like and contents of the pack**

The suspensions are pale yellow with a characteristic odour.

Respillin Oral Suspensions Sugar Free BP are available in bottles of 100ml.

### **Marketing Authorisation Holder and Manufacturer**

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

### **The product is distributed by: \*\***

PL 06453/0049 Respillin 125mg/5ml Oral Suspension Sugar Free BP

PL 06453/0050 Respillin 250mg/5ml Oral Suspension Sugar Free BP

**This leaflet was last revised in December 2015.**

\*\*This product is distributed by the following OLS:

Kent Pharmaceuticals Limited, Repton Road Measham, DE12 7DT, U.K. – hospital & retail  
Actavis, Barnstaple, EX32 8NS, UK – retail only  
Teva U.K. Limited, Eastbourne, BN22 9AG – retail only

## PATIENT INFORMATION LEAFLET

### **Pinamox (Amoxicillin Oral Suspension BP) 125mg/5ml Pinamox (Amoxicillin Oral Suspension BP) 250mg/5ml Amoxicillin (as amoxicillin trihydrate)**

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet

#### **What is in this leaflet**

1. What Pinamox Oral Suspension is and what it is used for
2. What you need to know before you take Pinamox Oral Suspension
3. How to take Pinamox Oral Suspension
4. Possible side effects
5. How to store Pinamox Oral Suspension
6. Contents of the pack and other information

#### **1. WHAT PINAMOX ORAL SUSPENSION IS AND WHAT IT IS USED FOR**

The name of your medicine is Pinamox. It is a powder for oral suspension. When prepared by the pharmacist, each bottle contains 100ml of suspension. Each 5ml spoonful of Pinamox contains either 125mg or 250mg of amoxicillin as amoxicillin trihydrate. Amoxicillin is one of a group of antibiotics called broad spectrum antibiotics. Pinamox is used to kill bacteria which cause infections in your body.

Pinamox can also be used to treat

- dental infections (abscesses)
- gonorrhoea (a sexually transmitted infection)
- prevent bacterial infections of the heart (bacterial endocarditis) following dental work or other operations in patients who have heart conditions or artificial heart valves.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PINAMOX ORAL SUSPENSION**

##### **Do not take Pinamox if you:**

- Have ever had a bad reaction or allergy to any penicillin-type antibiotic
- Have ever had a skin rash, swelling of the face or neck, or shortness of breath when taking any antibiotic
- Are allergic to amoxicillin or any of the other ingredients contained in this medicine (listed in section 6)

## **Warnings and precautions**

Check with your doctor or pharmacist before taking Pinamox if you:

- Suffer from kidney or liver problems
- Are suffering from glandular fever
- Are pregnant or breast-feeding, or planning pregnancy or breast-feeding
- Are not passing water regularly
- Have an intolerance to some sugars or have diabetes as this medicine contains sucrose

In newborn and premature babies, liver, kidney and blood functions should be closely monitored.

## **Other medicines and Pinamox**

Check with your doctor or pharmacist if you are taking, or have recently taken any other medicines even those not prescribed by a doctor. In particular tell your doctor if you are taking any of the following:

- Anticoagulants (medicines used to prevent blood clots e.g. warfarin and acenocoumarol)
- Medicines used to treat gout (which can be caused by the build up of uric acid) e.g. probenecid or allopurinol
- Some other antibiotics taken at the same time (e.g. tetracyclines, chloramphenicol, sulfonamides and erythromycin) may affect the way Pinamox oral suspension works.
- Methotrexate (used to treat tumours, Crohn's disease, psoriasis and rheumatoid arthritis)

## **Blood or urine tests**

If you or your child are having urine tests e.g. for diabetes (sugar in the urine) or blood tests e.g. for liver function let the doctor know that you or your child are taking Pinamox as amoxicillin can affect the results of these tests.

## **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

## **Driving and using machines**

This medicine is not likely to affect your ability to drive or operate machinery.

## **Pinamox contains sucrose**

Pinamox (Amoxicillin Oral Suspension) 125mg/5ml and 250mg/5ml contain 2.7g of sucrose per 5ml dose.

- This should be taken into account in patients with diabetes mellitus.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- May be harmful to the teeth (during long term use e.g. for two weeks or more)

Pinamox 250mg/5ml Oral Suspension contains 77.64mg of sodium per maximum 3g dose.

Pinamox 125mg/5ml Oral Suspension contains 90.96mg of sodium per maximum 3g dose.

To be taken into consideration by patients on a controlled sodium diet.

### **3. HOW TO TAKE PINAMOX ORAL SUSPENSION**

Follow all directions given to you by your doctor or pharmacist. Their directions may differ from the information contained in this leaflet. Your doctor may advise you to take your medicine in a different way, so you should always follow your doctor's advice about when and how to take your medicine and always read the label. Your pharmacist may be able to help if you are not sure.

Pinamox can be taken with or without food.

#### **Dosage**

You should follow your doctor's or prescriber's directions on how to take this product.

#### **Adults, children weighing over 40kg and older people:**

The total daily dose should not exceed 6g in total, given in divided doses.

- The usual dose for most infections is 5ml of Pinamox 250mg/5ml Oral Suspension to be taken 3 times a day.
- For more serious infections the dose may be doubled to 10ml of Pinamox 250mg/5ml Oral Suspension 3 times a day.
- High doses may be given in the following conditions:
  - Severe or recurrent chest infections: 3g twice daily
  - Simple urinary tract infections: two 3g doses with 10 to 12 hours between doses (short course)
  - Dental abscesses (infection under the gums and teeth): two 3g doses with 8 hours between doses
  - Gonorrhoea (a sexually transmitted infection): a single 3g dose
- For preventing infection during dental procedures or other surgery:  
3g Pinamox orally, 1 hour before the procedure. A second dose may be given 6 hours later, if considered necessary.

#### **Use in children weighing less than 40kg:**

**All doses are worked out depending on your child's body weight in kilograms.**

- Children weighing more than 40kg should receive the same as the adult dose
- Your doctor or pharmacist will advise you how much Pinamox you should give to your child
- The total daily dose should not exceed a total of 3g, given in divided doses.
- The usual recommended dose is 40mg – 90mg for each kilogram of body weight a day, given in two or three divided doses.
- For preventing infection during dental or surgical procedures: 50mg amoxicillin/kg body weight given as a single dose one hour before the procedure
- Tonsillitis (infection of the tonsils): 50mg/kg/day in divided doses
- Ear infections - your doctor will recommend the appropriate dose for you

#### **If you have kidney problems**

For patients with kidney problems, your doctor may prescribe a lower dose or choose a different medicine.

#### **Early Lyme disease (isolated erythema migrans):**

50 mg/kg/day in three divided doses, over 14-21 days.

**If you take more of your medicine than you should**

If you take more medicine than you should, tell your doctor immediately or go to the nearest hospital. You should take this leaflet and any medicine you still have to show the doctor. Severe cases of nausea, vomiting, and diarrhoea can be treated with rehydration therapy, by drinking fluids containing sodium, water and glucose to prevent dehydration, contact your doctor or pharmacist for further advice.

**If you forget to take your medicine**

If you forget to take a dose, take it as soon as you remember, unless it is within an hour of your next dose; then carry on as before. Do not take a double dose to make up for the dose you have missed.

**If you stop taking your medicine**

Keep taking this medicine until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine some bacteria may survive and cause the infection to come back or your condition may reoccur or get worse.

If you still feel unwell at the end of your course of treatment, tell your doctor.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects although not everybody gets them.

**If you experience any of the following events STOP taking your medicine and tell your doctor or go to your nearest hospital immediately:**

- Hypersensitivity or severe allergic reaction including swollen face or breathing problems. If these symptoms occur, STOP taking Pinamox right away and tell your doctor.
- Stevens-Johnson syndrome (a serious illness, signs of which may include blistering of the skin, mouth, eyes and genitals).
- Toxic epidermal necrolysis (a serious illness, signs of which may include blistering of the skin).
- Erythema multiforme - This is a skin reaction which involves itchy reddish purple lesions on the skin, often on the limbs.
- Acute generalised exanthematous pustulosis - This is a red rash with small blisters
- Hypersensitivity Vasculitis - This is a rash or pinpoint flat red round spots under the skin or bruising of the skin. This is due to inflammation of blood vessels caused by allergy
- A delayed allergic reaction can occur usually 7 to 12 days after having Pinamox, some signs include; rashes, fever, joint pains and enlargement of the lymph nodes especially under the arms.
- Allergic skin reactions with itching e.g. 'hives' or 'nettle rash'. If you start to itch or get a rash, STOP taking Pinamox and tell your doctor immediately.
- Severe diarrhoea possibly with bleeding (pseudomembranous colitis)
- Convulsions
- Notice your skin or the whites of your eyes turning yellow (jaundice), hepatitis (inflammation of the liver)
- Difficulty or discomfort in passing urine or having blood in the urine

**The following symptoms are less serious but you may wish to discuss them with your doctor if they become troublesome or last a long time.**

**Common side effects** (may affect up to 1 in 10 people):

- Nausea (feeling sick)
- Diarrhoea

**Uncommon side effects** (may affect up to 1 in 100 people):

- Vomiting (being sick)

**Very rare side effects** (may affect up to 1 in 10,000 people):

- Thrush (a yeast infection of the vagina, mouth or skin folds). You can get treatment for thrush from your doctor or pharmacist.
- Tooth discolouration. The colour usually returns to normal with brushing.
- Blackening of the tongue
- Excessive body movements (hyperkinesia) or dizziness
- Reduction (reversible) in blood cell counts that may result in anaemia (may be characterised by feeling weak or light-headed); or a longer time taken for blood to clot; or being more susceptible to infections
- Crystalluria, forming of crystals in the urine
- Change in liver enzymes
- Urine becoming darker or faeces becoming paler
- Meningitis (signs may include stiff neck, fever and vomiting)

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance,  
Earlsfort Terrace,  
IRL – Dublin 2,  
Tel: + 353 1 6764971;  
Fax: + 353 1 6762517;  
Website: [www.hpra.ie](http://www.hpra.ie);  
E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE PINAMOX ORAL SUSPENSION**

Do not use your medicine after the expiry date which is stated on the label (after abbreviation e.g. EXP.). The expiry date refers to the last day of that month.

Dry powder: Store in a dry place below 25°C. Store in the original container. Keep the bottle tightly closed.

Reconstituted suspension: Store for 7 days at 2°C-8°C in a refrigerator.

**KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.**

If your doctor tells you to stop your treatment, return any left over to the pharmacist. Only keep it if your doctor tells you to.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What your medicine contains**

Each 5ml spoonful of Pinamox (Amoxicillin Oral Suspension BP) contains either 125 mg or 250 mg of amoxicillin as amoxicillin trihydrate. Each bottle also contains sodium benzoate (E211), disodium edetate, sodium citrate anhydrous, lemon flavour powder, quinoline yellow (E104) and sucrose.

### **What your medicine looks like and the contents of the pack**

Your medicine comes in a bottle containing a pale yellow powder with the odour and flavour of lemon. The 125mg/5ml strength is available in bottles containing either 60ml or 100ml of suspension as prepared by the pharmacist. The 250mg/5ml strength is available in bottles containing 100ml of suspension as prepared by the pharmacist. A spoon with graduations of 1.25ml, 2.5ml and 5ml measures or a spoon with a 5ml graduation may be supplied with packs of this product.

Not all pack sizes may be marketed.

### **The product is made by:**

Your medicine is manufactured by Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

The marketing authorisations are also held by Athlone Laboratories Limited.

### **The product is distributed by:**

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

PA Number: PA 298/10/1 – Pinamox (Amoxicillin Oral Suspension BP) 125mg/5ml

PA Number: PA 298/10/2 – Pinamox (Amoxicillin Oral Suspension BP) 250mg/5ml

Date of last revision January 2016.