

## **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
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.

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**

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- 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.

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### **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)
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- typhoid and paratyphoid (fevers caused by a group of bacteria called *Salmonella*)
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- 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

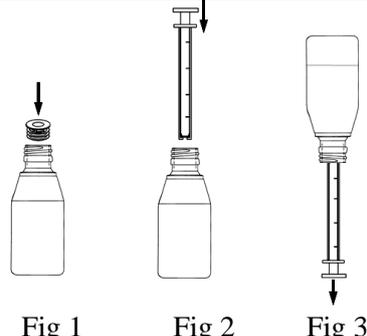
Check with your doctor before you take this medicine if you are pregnant or breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

## 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.

<p><b>TO THE PHARMACIST: INSTRUCTIONS FOR RECONSTITUTION OF THE POWDER</b></p> <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>Fig 1      Fig 2      Fig 3</p>
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## 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.
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  - Severe or recurrent chest infections: 3 g twice daily
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  - 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

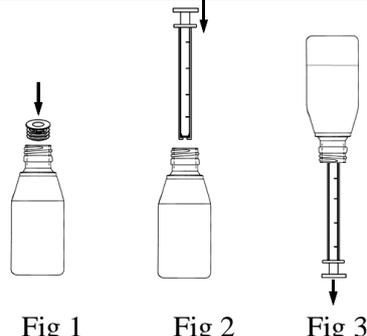
Check with your doctor before you take this medicine if you are pregnant or breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

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

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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.

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## **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
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- Nausea (feeling sick) or diarrhoea

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- 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**

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

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

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

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

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