

PACKAGE LEAFLET – INFORMATION FOR THE PATIENT

AMPICILLIN 125mg/5ml and 250mg/5ml ORAL SUSPENSION

Please 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 further questions, please ask your doctor or pharmacist (chemist).**
- **This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.**
- **If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. See section 4.**

WHAT IS IN THIS LEAFLET

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

1. WHAT AMPICILLIN ORAL SUSPENSION IS AND WHAT IT IS USED FOR

The name of your medicine is Ampicillin Oral Suspension. It belongs to a group of medicines called broad spectrum antibiotics. It is used to kill bacteria that cause infections in your body.

These infections include:

- Respiratory tract infections (e.g. infections of the nose and throat, pneumonia and bronchitis)
- Infections of the ear
- Urinary tract infections (e.g. infections of the bladder and urethra)
- Gastro-intestinal infections (e.g. infections of the intestines)
- Enteric/Typhoid fever (infectious disease contracted by eating food or drinking water contaminated with *Salmonella*)
- Gynaecological infections and Gonorrhoea (a sexually transmitted disease)
- Infections of the blood (Septicaemia)
- Skin and soft tissue (e.g. Acne)
- To prevent endocarditis (inflammation of the lining of the heart and its valves) after surgery or a dental procedure
- Peritonitis (an inflammation of the peritoneum, the tissue that lines the inner wall of the abdomen)
- Meningitis (inflammation of the protective membranes covering the brain and spinal cord)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMPICILLIN ORAL SUSPENSION

Do not take this medicine if:

- You have ever had an allergic reaction to Ampicillin, beta lactam antibiotics or any other penicillin or cephalosporin-type antibiotics (see symptoms in Section 4, Possible Side Effects)
- You have ever had an allergic reaction to any of the other ingredients of this medicine - (see list of ingredients in Section 6, Contents of the pack and other information).

Warnings and precautions:

Talk to your doctor or pharmacist before taking your medicine if:

- You suffer from kidney problems as you may require a lower dose than normal
- You are suffering from glandular fever or cytomegalovirus (CMV) infection
- You are suffering from lymphatic leukaemia, HIV or syphilis

Other medicines and Ampicillin Oral Suspension

Your medicine may affect the way other medicines work. Please inform your doctor or your pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription, especially the following:

- Allopurinol, sulfinpyrazone or probenecid (used to treat gout)
- Tetracycline, erythromycin and chloramphenicol (other types of antibiotics)
- Anticoagulants e.g. warfarin or phenindione
- Cytotoxic drugs e.g. methotrexate (used to treat rheumatoid arthritis, psoriasis, or malignant diseases such as lymphatic leukaemia)
- Chloroquine (used for prevention and treatment of malaria)
- Oral typhoid vaccine (used to prevent typhoid)

Tests

While you are taking Ampicillin, the results of certain medical tests could be affected. If you are having blood or urine tests, please tell your doctor that you are taking Ampicillin.

Pregnancy and breastfeeding

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

Important information about some of the ingredients in your medicine:

This medicine contains up to 1.937g of sucrose (sugar) per 5ml dose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Ponceau 4R (**E124**) can cause allergic-type reactions including asthma. Allergy is more common in patients who are allergic to aspirin.

3. HOW TO TAKE AMPICILLIN ORAL SUSPENSION

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Take your medicine on an empty stomach, at least thirty minutes to one hour before meals/food. It is important that you take your medicine at the right times.

The dose will depend on the patient and will be decided by your doctor. However, the usual doses for each illness are:

Adults (including the elderly)

- Ear, nose and throat: 250mg four times daily
- Bronchitis: 250mg four times daily.
This may be increased to 1 gram four times daily in certain cases.
- Pneumonia: 500mg four times daily
- Urinary tract infections: 500mg three times daily
- Gastro-intestinal infections: 500-750 mg three to four times daily
- Typhoid fevers: Acute: 1-2 grams four times daily for 2 weeks
Carriers: 1-2 grams four times daily for 4 to 12 weeks

- Gonorrhoea: 2 grams orally with 1 gram of probenecid as single dose.
A repeated dose may be necessary in females.

The dosage may be reduced in patients with severe kidney failure.

Children under 10 years

Children usually take half the adult dose.

If you take more of your medicine than you should

If you (or somebody else) accidentally takes too much of your medicine, speak to your doctor or pharmacist immediately.

If you forget to take your medicine

If you forget to take a dose, take it as soon as you remember, 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 your medicine until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, your infection may return or get worse. If you are still unwell after taking all the medicine, go and see your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ampicillin can cause side effects, although not everybody gets them. If they occur, they are likely to be temporary, and not serious. However, some may be serious and need medical attention.

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 called anaphylaxis, which causes difficulty breathing
- Swelling of the lips, cheeks, tongue and eyelids
- Skin rash, itching or any other skin trouble, such as blisters and swollen red patches or hives. These reactions may occur if you have glandular fever, cytomegalovirus (CMV) infection, lymphatic leukaemia or HIV infection
- Yellowing of the whites of the eyes and skin
- Difficulty or discomfort in passing urine, having blood in the urine or lower back pain (may be a sign of kidney inflammation)
- Pseudomembraneous colitis (severe diarrhoea which may contain blood or mucous)

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

Common side effects (i.e. have been reported in more than 1 in 100 people taking it) include:

- Diarrhoea
- Nausea and vomiting (feeling and being sick)

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

- Fever
- Joint and muscle pain
- Temporary blood disorders that could cause you to have more infections such as fever, severe chills, sore throat, mouth ulcers or bruising more easily. It can also cause anaemia, this can make your skin pale, cause weakness, breathlessness and tiredness

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

5. HOW TO STORE AMPICILLIN ORAL SUSPENSION

Do not use this medicine after the expiry date shown on the label.

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN Store in its original container and keep the bottle tightly closed in order to protect from light and moisture.

Dry powder: Store below 25°C.

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

Return any left-over medicine to the pharmacist. 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 Ampicillin Oral Suspension contains

Ampicillin Oral Suspension is available in two strengths containing either 125mg/5ml or 250mg/5ml of the active ingredient ampicillin as ampicillin trihydrate.

The suspensions also contain colloidal anhydrous silica, sodium benzoate (**E211**), croscarmellose sodium, sodium citrate anhydrous, ponceau 4R (**E124**), cherry flavour and sucrose. Please see further information on ingredients in section 2.

What Ampicillin Oral Suspension looks like and contents of the pack

Dry powder: an off white granular powder with a characteristic odour of cherry.

Reconstituted suspension: a light pink coloured suspension with a characteristic odour of cherry. The 125mg strength medicine is available in bottles containing 60ml or 100ml of oral suspension while the 250mg strength medicine is available only in packs containing 100ml of oral suspension.

The licence holder and manufacturer:

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

Telephone: 00 353 (0) 90 666 1109

Fax: 00 353 90 (0) 90 666 1921

Distributed by:*

Ampicillin 125mg/5ml Oral Suspension PL 06453/0004

Ampicillin 250mg/5ml Oral Suspension PL 06453/0005

This leaflet was last revised Feb 16.

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

PACKAGE LEAFLET – INFORMATION FOR THE PATIENT (AMPITRIN)

AMPITRIN 125mg/5ml and 250mg/5ml ORAL SUSPENSION

Please 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 further questions, please 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 symptoms are the same as yours.**
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WHAT IS IN THIS LEAFLET

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2. What you need to know before you take Ampitrin Oral Suspension
3. How to take Ampitrin Oral Suspension
4. Possible side effects
5. How to store Ampitrin Oral Suspension
6. Contents of the pack and other information

1. WHAT AMPITRIN ORAL SUSPENSION IS AND WHAT IT IS USED FOR

The name of your medicine is Ampitrin Oral Suspension. It belongs to a group of medicines called broad spectrum antibiotics. It is used to kill bacteria that cause infections in your body.

These infections include:

- Respiratory tract infections (e.g. infections of the nose and throat, pneumonia and bronchitis)
- Infections of the ear
- Urinary tract infections (e.g. infections of the bladder and urethra)
- Gastro-intestinal infections (e.g. infections of the intestines)
- Enteric/Typhoid fever (infectious disease contracted by eating food or drinking water contaminated with *Salmonella*)
- Gynaecological infections and Gonorrhoea (a sexually transmitted disease)
- Infections of the blood (Septicaemia)
- Skin and soft tissue (e.g. acne)
- To prevent endocarditis (inflammation of the lining of the heart and its valves) after surgery or a dental procedure
- Peritonitis (an inflammation of the peritoneum, the thin tissue that lines the inner wall of the abdomen)
- Meningitis (inflammation of the protective membranes covering the brain and spinal cord)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMPITRIN ORAL SUSPENSION

Do not take this medicine if:

- You have ever had an allergic reaction to ampicillin, beta lactam antibiotics, or any other penicillin or cephalosporin-type antibiotics (see symptoms in Section 4, Possible Side Effects)
- You have ever had an allergic reaction to any of the other ingredients of the medicine - (see list of ingredients in Section 6, Contents of the pack and other information).

Warnings and precautions Talk to your doctor or pharmacist before taking your medicine if:

- You suffer from kidney problems as you may require a lower dose than normal
- You are suffering from glandular fever or cytomegalovirus (CMV) infection
- You are suffering from lymphatic leukaemia, HIV or syphilis

Other medicines and Ampitrin Oral Suspension

Your medicine may affect the way other medicines work. Please inform your doctor or your pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription, especially the following:

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- Tetracycline, erythromycin and chloramphenicol (other types of antibiotics)
- Anticoagulants e.g. warfarin or phenindione
- Cytotoxic drugs e.g. methotrexate (used to treat rheumatoid arthritis, psoriasis, or malignant diseases such as lymphatic leukaemia)
- Chloroquine (used for prevention and treatment of malaria)
- Oral typhoid vaccine (used to prevent typhoid)

Tests

While you are taking Ampitrin, the results of certain medical tests could be affected. If you are having blood or urine tests, please tell your doctor that you are taking Ampitrin.

Pregnancy and breastfeeding

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

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Ponceau 4R (**E124**) can cause allergic-type reactions including asthma. Allergy is more common in patients who are allergic to aspirin.

3. HOW TO TAKE AMPITRIN ORAL SUSPENSION

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- Pneumonia: 500mg four times daily
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- Gastro-intestinal infections: 500-750 mg three to four times daily
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- Skin rash, itching or any other skin trouble, such as blisters and swollen red patches or hives. These reactions may occur if you have glandular fever, cytomegalovirus (CMV) infection, lymphatic leukaemia or HIV infection and are also taking Ampitrin.
- Yellowing of the whites of the eyes and skin
- Difficulty or discomfort in passing urine, having blood in the urine or lower back pain (may be a sign of kidney inflammation)
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