PACKAGE LEAFLET – INFORMATION FOR THE PATIENT

Ampicillin 250mg and 500mg Capsules

Please read 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.
- 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 Capsules are and what they are used for
- 2. What you need to know before you take Ampicillin Capsules
- 3. How to take Ampicillin Capsules
- 4. Possible side effects
- 5. How to store Ampicillin Capsules
- 6. Contents of the pack and other information

1. WHAT AMPICILLIN CAPSULES ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Ampicillin Capsules. 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:

- o Respiratory tract infections (e.g. infections of the nose and throat, pneumonia, bronchitis)
- o Infections of the ear
- o Urinary tract infections (e.g. infections of the bladder and urethra)
- o Gastro- intestinal infections (e.g. infections of the intestines)
- Enteric/Typhoid fever (an infectious disease contracted by eating food or drinking water contaminated with Salmonella)
- o Gynaecological infections and Gonorrhoea (a sexually transmitted disease)
- o Infections of the blood (Septicaemia)
- o 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)
- o Meningitis (inflammation of the protective membranes covering the brain and spinal cord)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMPICILLIN CAPSULES

Do not take this medicine if you:

- o 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)
- o 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:

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

Other medicines and Ampicillin Capsules

Your medicine may interfere with other medicines you are taking. Please inform your doctor or your pharmacist if you are taking, or have recently taken, any other medicines even those not prescribed – especially any of the following:

- o Allopurinol, sulfinpyrazone or probenecid (used to treat gout)
- o Tetracycline, erythromycin and chloramphenicol (other types of antibiotics)
- o Anticoagulants e.g. warfarin or phenindione
- O Cytotoxic drugs e.g. methotrexate (used to treat rheumatoid arthritis, psoriasis, or malignant diseases such as lymphatic leukaemia.)
- o Chloroquine (used for prevention and treatment of malaria)
- o Oral typhoid vaccine (used to prevent typhoid)
- The oral contraceptive pill, Ampicillin may interfere with the action of the contraceptive pill. Therefore additional contraceptive measures should be taken during and for 7 days after taking this medicine.

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.

3. HOW TO TAKE AMPICILLIN CAPSULES

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. The capsules should be taken orally 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 1gram four times daily in certain cases.

Pneumonia: 500mg four times daily
 Urinary tract infections: 500mg three times daily

• Gastro-intestinal infections: 500 - 750mg 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 a 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
- o 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 or lymphatic leukaemia and are also taking ampicillin.
- o Yellowing of the whites of the eyes and skin
- O Difficulty or discomfort in passing urine, having blood in the urine or lower back pain (may be a sign of kidney inflammation)
- o Pseudomembraneous colitis (severe diarrhoea which may contain blood or mucous).

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 (i.e. have been reported in more than 1 in 100 people) 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:

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 CAPSULES

Store below 25°C. Protect from light and moisture. Store in the original package.

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN. Do not use this medicine after the expiry date shown on the label.

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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ampicillin Capsules contain

Active ingredient: ampicillin as ampicillin trihydrate

Other ingredients: magnesium stearate and gelatin (black iron oxide (E172), quinoline yellow (E104),

titanium dioxide (E171), patent blue V (E131) and erythrosine (E127) as colouring agents).

What Ampicillin Capsules look like and contents of the pack

250mg Capsule - red and grey capsule with 'AMP 250' printed on it. 500mg Capsule - red and grey capsule with 'AMP 500' printed on it.

Both strengths are available in the following pack sizes:

Tubs are available in pack sizes of 15, 18, 20, 21, 28, 30, 50, 100 & 500 capsules.

Blister packs are available in pack sizes of 15, 18, 20, 21, 28, 30, 50, 100 & 500 capsules.

The 250mg capsule is also available in pack size 1000.

The 500mg capsule is also available in pack size 16 in blisters.

Not all pack sizes may be marketed.

The manufacturer and licence holder

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

Telephone: 00 353 (0) 90 666 1109

Fax: 00 353 (0) 90 666 1921

Distributed by:

*

PL 06453/0007 PL 06453/0008

This leaflet was last revised July 2014.

*Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K. or Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland. (not commercialised)