Amoxicillin 250mg & 500mg Capsules

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PHARMA CODE

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Pharmacode Reading Direction

Amoxicillin 250mg and 500mg Capsules
(Amoxicillin Trihydrate)

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

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

1. WHAT AMOXICILLIN CAPSULE IS AND WHAT IT IS USED FOR

The name of this medicine is Amoxicillin Capsules.
The active substance in Amoxicillin Capsule is called amoxicillin trihydrate, which belongs to a group of antibiotics called broad-spectrum penicillins.

Amoxicillin Capsule is used to treat infections caused by bacteria in different parts of the body. Amoxicillin may also be used in combination with other medicines to treat stomach ulcers.

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

Do not take Amoxicillin Capsules
- if you are allergic to amoxicillin, penicillin or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had an allergic reaction to any antibiotic. This can include a skin rash or swelling of the face or throat.

Talk to your doctor before taking this product if any of the above apply to you.

Warnings and Precautions
Talk to your doctor or pharmacist before taking Amoxicillin Capsules:
- have glandular fever (fever, sore throat, swollen glands and extreme tiredness)
- if you suffer from kidney disease
- are not urinating regularly.

If any of the above apply to you, it is important that you tell your doctor or pharmacist before taking Amoxicillin Capsules and they will decide what to do.

Blood and Urine tests
If you are having:
- Urine tests (glucose) or blood tests for liver function
- Oestriol tests (used during pregnancy to check the baby is developing normally)

Tell your doctor or pharmacist that you are taking Amoxicillin. This is because Amoxicillin can affect the results of these tests.

Other medicines and Amoxicillin Capsules
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
- If you are taking allopurinol (used for gout) with Amoxicillin, it may be more likely that you will have an allergic skin reaction.
- If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Amoxicillin.
- If you are taking medicines to help stop blood clots (such as warfarin), you may need extra blood tests.
- If you are taking other antibiotics (such as tetracycline) Amoxicillin may be less effective.
- If you are taking methotrexate (used for the treatment of cancer and severe psoriasis) Amoxicillin may cause an increase in side effects.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking Amoxicillin Capsules or any other medicine, during pregnancy or while breast-feeding or if you are planning to have a baby.

Driving and using machines
Amoxicillin can have side effects and the symptoms (such as allergic reactions, dizziness and convulsions) may make you unfit to drive.
Do not drive or operate machinery unless you are feeling well.

3. HOW TO TAKE AMOXICILLIN CAPSULES

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Swallow with water without opening capsule.
- Space the doses evenly during the day, at least 4 hours apart.

The usual dose is:
Use in children weighing less than 40 kg
All doses are worked out depending on the child's bodyweight in kilograms
- Your doctor will advise you how much Amoxicillin Capsules you should give to your child
- The usual dose is 40mg to 90mg for each kilogram of body weight per day, given in two or three divided doses.
- The maximum recommended dose is 100 mg for each kilogram of body weight a day.

Adults, elderly patients and children weighing 40 kg or more
The usual dose of Amoxicillin Capsule is 250 mg to 500 mg three times a day or 750 mg to 1 g every 12 hours, depending on the severity and type of infection.
- **Severe infections:** 750 mg to 1 g three times a day.
- **Urinary tract infection:** 3 g twice daily for one day.
- **Lyme disease (an infection spread by parasites called ticks):** Isolated erythema migrans (early stage – red or pink circular rash): 4 g a day, Systemic manifestations (late stage – for more serious symptoms or when the disease spreads around your body): up to 6 g a day.
- **Stomach ulcers:** one 750 mg or one 1 g dose twice a day for 7 days with other antibiotics and medicines to treat stomach ulcers.
- **To prevent heart infection during surgery:** the dose will vary according to the type of surgery.

Other medicines may also be given at the same time.
Your doctor, pharmacist or nurse can give you more details.
- The maximum recommended dose is 6 g per day.

Kidney problems
If you have kidney problems the dose might be lower than the usual dose.

If you take more Amoxicillin than you should
If you have taken too much Amoxicillin signs might be an upset stomach (feeling sick, being sick or diarrhoea) or crystals in the urine, which may be seen as cloudy urine, or problems urinating. Talk to your doctor as soon as possible. Take the medicine to show the doctor.

If you forget to take Amoxicillin Capsules
- If you forget to take a dose, take it as soon as you remember.
- Do not take the next dose too soon, wait about 4 hours before taking the next dose.
- Do not take a double dose to make up for a forgotten dose.

How long should you take Amoxicillin Capsule for?
- Keep taking Amoxicillin Capsule for as long as your doctor has told you to, even if you feel better. You need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.
- Once you finish treatment, if you still feel unwell you should go back to see the doctor.

Thrush (a yeast infection of moist areas of the body which can cause soreness, itching and white discharge) may develop if Amoxicillin Capsule is used for a long time. If this occurs tell your doctor.

If you take Amoxicillin Capsule for a long time, your doctor may perform additional tests to check your kidneys, liver and blood are working normally.

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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.
Stop taking Amoxicillin Capsule and see a doctor straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:

The following are very rare (may affect up to 1 in 10,000 people)
- allergic reactions, the signs may include: skin itching or rash, swelling of the face, lips, tongue, body or breathing difficulties. These can be serious and occasionally deaths have occurred.
- rash or pinpoint flat red round spots under the skin surface or bruising of the skin. This is due to inflammation of blood vessel walls due to an allergic reaction. It can be associated with joint pain (arthritis) and kidney problems
- a delayed allergic reaction can occur usually 7 to 12 days after having Amoxicillin Capsule, some signs include: rashes, fever, joint pains and enlargement of the lymph nodes especially under the arms.
- a skin reaction known as 'erythema multiforme' where you may develop: itchy reddish purple patches on the skin especially on the palms of the hands or soles of the feet, 'hive-like' raised swollen areas on the skin, tender areas on the surfaces of the mouth, eyes and genitals. You may have a fever and be very tired.
- other severe skin reactions can include: changes in skin colour, bumps under the skin, blistering, pustules, peeling, redness, pain, itching, scaling. These may be associated with fever, headaches and body aches.
- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) [Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)].
- fever, chills, a sore throat or other signs of an infection, or if you bruise easily. These may be signs of a problem with your blood cells.
- the *Jarisch-Herxheimer* reaction which occurs during treatment with Amoxicillin Capsule for Lyme disease and causes fever, chills, headache, muscle pain and skin rash.
- inflammation of the large bowel (colon) with diarrhoea (sometimes containing blood), pain and fever.
- serious liver side effects may occur. They are mainly associated with people having treatment over a long period, males and the elderly. You must tell your doctor urgently if you get:
- severe diarrhoea with bleeding
- blisters, redness or bruising of the skin
- darker urine or paler stools
- yellowing of the skin or the whites of the eyes (jaundice). See also anaemia below which might result in jaundice.

These can happen when having the medicine or for up to several weeks after.

If any of the above happens stop taking the medicine and see your doctor straight away.

Sometimes you may get less severe skin reactions such as:
- a mildly itchy rash (round, pink-red patches), 'hive-like' swollen areas on forearms, legs, palms, hands or feet. This is uncommon (may affect up to 1 in 100 people).

If you have any of these talk to your doctor as Amoxicillin Capsule will need to be stopped.

The other possible side effects are:
Common (may affect up to 1 in 10 people)
- skin rash
- feeling sick (nausea)
- diarrhoea

Uncommon (may affect up to 1 in 100 people)
- being sick (vomiting)

Very rare (may affects 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
- kidney problems
- fits (convulsions), seen in patients on high doses or with kidney problems
- dizziness
- hyperactivity
- crystals in the urine, which may be seen as cloudy urine, or difficulty or discomfort in passing urine. Make sure you drink plenty of fluids to reduce the chance of these symptoms
- the tongue may change to yellow, brown or black and it may have a hairy appearance
- an excessive breakdown of red blood cells causing a type of anaemia. Signs include: tiredness, headaches, shortness of breath, dizziness, looking pale and yellowing of the skin and the whites of the eyes
- low number of white blood cells
- low number of cells involved with blood clotting
- the blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or cut yourself.
- inflammation of the protective membrane surrounding the brain (aseptic meningitis).

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 or by searching for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE AMOXICILLIN CAPSULES

Keep this medicine out of the sight and reach of children.
Do not use Amoxicillin Capsules after the expiry date that is stated on the carton and blister foil. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.
Do not use Amoxicillin Capsules if you notice that the pack or any of the capsules are damaged. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Amoxicillin Capsules contains
- The active substance in Amoxicillin Capsules is called amoxicillin. The capsules contain either 250mg or 500mg of amoxicillin as amoxicillin trihydrate
- The other ingredients are sodium lauryl sulphate and magnesium stearate
- The capsule shells are made of gelatin, SLS and contain erythrosine (E127), indigotine (E132) and titanium dioxide (E171) as colouring agents.

What Amoxicillin Capsules looks like and the contents of the pack
Amoxicillin Capsules 250mg are White/Maroon size '2' capsules containing white to yellowish granular powder.
Amoxicillin Capsules 500mg are White/Maroon size '0' capsules containing white to yellowish granular powder.
Amoxicillin Capsules 250mg and 500mg are available in
- containers of 3, 100, 250, 500 and 1000 capsules
- blister packs of 15 and 21 capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Flamingo Pharma (UK) Ltd.
1st Floor, Kirkland House, 11-15 Peterborough Road,
Harrow, Middlesex, HA1 2AX, UK

Manufacturer:
Flamingo Pharma (UK) Limited,
The Bloc,
38 Springfield Way,
Anlaby, Hull,
HU10 6RJ, United Kingdom.

If you would like this leaflet in different format information or want to report any side effect please contact marketing authorization holder listed above

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