

AMOXICILLIN

Read this leaflet before taking this medicine. Keep this leaflet; you may need to read it again. If you have any further questions, ask your doctor or pharmacist. Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

COMPOSITION: AMOXICILLIN capsules and suspensions contain amoxicillin trihydrate. This belongs to a group of antibiotics called penicillins.

INDICATIONS: AMOXICILLIN is used to treat infections in different parts of the body caused by bacteria. It is also used to stop infections when you have a tooth removed or other surgery. AMOXICILLIN may also be used in combination with other medicines to treat stomach ulcers.

CONTRA-INDICATIONS: Do not take AMOXICILLIN if you are allergic (hypersensitive) to amoxicillin, penicillin or any of the other ingredients.

PRECAUTIONS: Before administration, tell your doctor if:

- You are allergic to penicillin or any other antibiotic, or you ever had a skin rash or swelling of the face or neck when taking any antibiotic.
- You are taking a contraceptive pill (extra precautions may be needed).
- You have or you think you have glandular fever.
- You have been treated for kidney problems, or you are not passing water regularly.
- You are taking other medicines (such as warfarin, allopurinol, probenecid or even herbal medicines).

Consult your doctor or pharmacist before taking any medicine if you think you might be or if you are pregnant, or if you are breast feeding.

DOSAGE AND ADMINISTRATION: Always follow your doctor's instructions. Usual adult, elderly and children weighing over 40kg dosage: 250 to 500mg every 8 hours depending on bodyweight and severity of condition.

Severe or recurrent chest infection: 3g (6 x 500mg capsules) twice a day.

Urinary tract infection: 2 x 3g dose (6 x 500mg capsules) at 10 to 12 hours apart.

Dental abscess (infection under the gums and teeth): 2 x 3g doses (6 x 500mg capsules) at 8 hours between each dose.

Gonorrhoea (a sexually transmitted infection): 1 x 3g dose (6 x 500mg capsules).

Stomach ulcers: 1 x 750mg dose (3 x 250mg capsules or 1 x 500mg capsule and 1 x 250mg capsule) or 1 x 1g dose (2 x 500mg capsules) twice a day for 7 days with other antibiotics.

Children weighing less than 40kg: Usual dose: 40-90mg for each kilogram of body weight a day in two or three divided doses spread apart as directed by the doctor.

Lower doses may be needed for patients with kidney problems.

Dosage should be spread evenly within the day, and swallowed with a glass of water at the start of a meal or slightly before.

Keep taking your medicine until your prescribed course is finished 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. Treatment should be continued for 2 to 3 days after the symptoms have gone. Do not take AMOXICILLIN for more than 2 weeks. If you still feel unwell you should go back to see the doctor. Thrush (a yeast infection of moist areas of the body) may develop if AMOXICILLIN is used for a long time. If this occurs, tell your doctor.

If you forget to take a dose: Take it as soon as you remember. Don't take the next dose too soon, wait about 4 hours before taking the next dose.

MANAGEMENT OF OVERDOSE: If a large amount is taken, consult your doctor or casualty department at once.

POSSIBLE SIDE EFFECTS: Like all medicines, Amoxicillin can cause side effects, although not everybody gets them. Stop taking Amoxicillin 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:

- 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, 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 private parts. 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

• High temperature (fever), chills, a sore throat or other signs of an infection, or easy bruising. These may be signs of a problem with your blood cells.

• Inflammation of the large bowel (colon) with diarrhoea sometimes containing blood, pain and fever.

• Serious liver side effects may occur which are often reversible. 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.
- Darker urine or paler stools.
- Blisters, redness or bruising of the skin.
- 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 happen 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. If you have any of these talk to your doctor as Amoxicillin will need to be stopped.

The other possible side effects are:

Common:

- Skin rash
- Feeling sick (nausea)
- Diarrhoea

Uncommon:

- Being sick (vomiting)

Very rare:

- 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

- Teeth may appear stained, usually returning to normal with brushing (this has been reported in children)
- 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 form of anaemia. Signs include: tiredness, headaches, shortness of breath, dizziness, looking pale and yellowing of the skin and the whites of the eyes
- The blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or cut yourself.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

STORAGE: Keep this medicine out of the reach of children, in a dark, dry and cool place (under 25°C). Do not use after the expiry date written on the outer box or if there are signs of deterioration. Do not keep expired or no longer needed medicines. Do not dispose via wastewater or household waste. Ask your pharmacist how to dispose no longer needed medicines. Keep the reconstituted syrup in the refrigerator (7°C) and use it within 14 days from reconstitution.

SUPPLY: AMOXICILLIN is available as:

CAPSULES (Maroon/Grey) containing Amoxicillin trihydrate equiv. to 250mg or 500mg in boxes of 10, 20, 30, 100, 500 or 1000 capsules.

SUSPENSIONS: Dry powder giving when reconstituted with drinking water, amoxicillin trihydrate suspension equivalent to 125mg/5ml, 250mg/5ml or 500mg/5ml in bottles of 60 or 100ml

EXCIPIENTS: Capsules: Magnesium stearate, purified talc, colloidal silicon dioxide, gelatin, black iron oxide, titanium dioxide, quinolone yellow, Erythrosine FD&C Red 3.

Suspensions: Sucrose, carmellose sodium, citric acid, methyl p-hydroxybenzoate, propyl p-hydroxybenzoate, raspberry and vanilla flavour, erythrosine lake.

Marketing Authorisation Holder

Κάτοχος Άδειας Κυκλοφορίας

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ΑΝΑΘΕΩΡΗΘΗΚΕ/REVISED: MAR 2015