

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

AMOXICILLIN 3G SACHET SUGAR FREE

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, 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 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
- blood (septicaemia)
- abdomen (intra-abdominal sepsis and peritonitis)
- gonorrhoea (a sexually transmitted infection)
- the bladder or the urethra (the tube which carries urine from the bladder)
- typhoid and paratyphoid (fevers caused by a group of bacteria called salmonella)
- the female reproductive system including infections associated with pregnancy and childbirth (puerperal sepsis and septic abortion)
- tonsils (tonsillitis)
- sinuses (sinusitis)
- heart (endocarditis)
- skin, bone, teeth and gums (abscesses)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMOXICILLIN

Do not take Amoxicillin if:

- You have ever had a bad reaction or allergy to any penicillin-type antibiotic
- You have ever had a skin rash, swelling of the face or neck or shortness of breath when taking any antibiotic
- You are allergic to any of the ingredients contained in this medicine (listed in section 6)
- You have an intolerance to some sugars (hereditary fructose intolerance)

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 urine regularly.

Other medicines and Amoxicillin

Tell your doctor or pharmacist if you are taking, or have recently taken any other medicines even those not prescribed by a doctor. In particular tell your doctor if you are taking any of the following:

- Anticoagulants used to thin your blood e.g. Warfarin, Acenocoumarol
- Chemotherapy drugs used to treat cancer e.g. Methotrexate
- Drugs used to treat gout e.g. Probenecid, Allopurinol, Sulfapyridine
- Oral typhoid vaccine (may not work if taken with amoxicillin)

Having urine or blood tests

If you 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.

Important information about some of the ingredients in your medicine

Each sachet contains 5.4g (grams) of 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.

The maximum single dose of 6g of Amoxicillin contains 11g of sorbitol.

May have a mild laxative effect. Calorific value 2.6 kcal/g sorbitol.

The maximum single dose of 6g of Amoxicillin contains 149mg of sodium. To be taken into consideration by patients on a controlled sodium diet.

3. HOW TO TAKE AMOXICILLIN

Always take this medicine exactly as your doctor or pharmacist has told you. Their directions may differ from the information contained in this leaflet. Your doctor may advise you to take your medicine in a different way, so you should always follow your doctor's advice about when and how to take your medicine and always read the label. Your pharmacist may be able to help if you are not sure.

You should empty the powder from the sachet into a glass of water, stir the mixture and swallow it at once. You may take the medicine with or after food, unless the label advises a specific time.

The highest recommended adult dose is 3g (one sachet) *twice* a day. These high dose sachets are not suitable for children.

Adult (including the elderly) dose:

- For severe or recurrent chest infections a dose of 3g twice daily given orally is usually recommended
- For simple urinary tract infections the adult dose is two 3g doses given orally with 10 to 12 hours between doses (short course)
- For the treatment of dental abscesses two 3g doses given orally with 8 hours between doses is recommended
- For gonorrhoea a single 3g dose given orally is recommended

The following are the usual adult dosages for preventing infection during dental procedures and other surgery:

- If a general anaesthetic is not used, 3g given orally one hour before surgery and another dose six hours later if necessary
- If a general anaesthetic is used, 3g given orally four hours before anaesthesia and 3g six hours after the initial dose

If you have kidney problems, you may have to take a lower dose than those above, and it may be more suitable to take the medicine in another form.

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 take more Amoxicillin than you should

If too many of the sachets have been swallowed, or you think a child has accidentally swallowed any, contact your nearest hospital casualty department or doctor immediately.

You should take this leaflet and any sachets 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.

REMEMBER:

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.

You should make sure you have several more drinks of water each day unless told otherwise by a doctor.

If you are still unwell after taking all the medicine, go and see your doctor. Never give or take more than the recommended dose each day.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. 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 including swollen face or breathing problems. If these symptoms occur, STOP taking amoxicillin right away and tell your doctor.
- Severe diarrhoea 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
- Notice your urine becoming darker or your faeces becoming paler
- Notice your skin or the white of your eyes turning yellow (jaundice)
- Difficulty or discomfort in passing urine or having cloudy urine

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: may affect up to 1 in 10 people

- Nausea (feeling sick) or diarrhoea

Uncommon: may affect up to 1 in 100 people

- Vomiting

Very rare: may affect 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 pharmacist.
- Crystalluria, forming of crystals in the urine
- Excessive body movements (hyperkinesia), dizziness or convulsions.
- Tooth discolouration. The colour usually returns to normal with brushing.

- Blackening of the tongue
- Inflammation of the kidneys (cause pain in the lower back, blood in the urine or decreased urine output)
- Inflammation of the liver (hepatitis)
- Reduction (reversible) in blood cell counts including anaemia (a reduction in the body's red blood cells or haemoglobin which 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.

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

5. HOW TO STORE AMOXICILLIN

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

Do not store above 25°C. Store in the original package.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

If your doctor tells you to stop your treatment, return any left over to the pharmacist. Only keep it if your doctor tells you to.

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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

The powder in Amoxicillin 3g Sachet Sugar Free is a cream / pale yellow colour.

Each sachet contains 3g Amoxicillin as amoxicillin trihydrate. It also contains sodium citrate, disodium edetate, colloidal anhydrous silica, sorbitol, lemon flavour powder, quinoline yellow (E104) and xanthan gum.

The sachets are available in boxes of 2 and 14.

Your medicine is manufactured by:

Laboratorio REIG JOFRE, Calle Jarama, s/n, Poligono Industrial, 45007 Toledo, Spain.

The Product Licence Holder is:

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

The Product is distributed by:*

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

*Almus Pharmaceuticals, 43 Cox Lane, Chessington, KT9 1SN, UK.

PL 06453/0054

Date of last revision: December 2015