

BIOXICILLIN 500mg

Amoxicillin 500 mg

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further question, 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 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.

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1. WHAT BIOXICILLIN IS AND WHAT IT IS USED FOR

Amoxicillin is an antibiotic used to treat infections. It belongs to a class of medicines called "penicillins".

Amoxicillin may treat many different types of infections: infections of respiratory tract (bronchitis, pneumonia), ear infections (otitis), urinary bladder and kidney infections (pyelonephritis, cystitis, urethritis), female reproductive system infections, abdominal infections, heart infections (endocarditis), skin infections, tooth and gum infections (dental abscess).

Also, amoxicillin may be used in the treatment of typhoid and paratyphoid fevers (caused by Salmonella).

Amoxicillin may be used in combination with other medicines to treat duodenal and gastric ulcers.

2. BEFORE YOU TAKE BIOXICILLIN

Do not take Bioxillin:

- if you are allergic (hypersensitive) to amoxicillin, other penicillin-like antibiotics, cephalosporins or any of the drug ingredients;
- if you have a disease caused by a virus called Epstein-Barr, characterized by fever, inflammation of ganglions, splenomegaly, inflammation of pharynx and amygdalae;
- if you suffer of chronic lymphoid leukemia (blood disease characterized by excess of white blood cells);
- in children under 6 years of age.

Take special care with Bioxillin

- if you have bronchial asthma;
- if you have or have ever had skin eruptions when using antibiotics;
- if you have frequent stools with blood marks, abdominal pains and fever during the treatment with amoxicillin;
- if you have primary syphilis (painless skin lesions, usually localized at the level of genitals and characterized by inflammation of adjacent ganglia);
- if you have liver disorders;
- if you have kidney disorders;
- if you have diabetes, and urine glucose test is carried out by colorimetric methods;
- if you are going to make a test to detect the antibodies attached to your red blood cells (Coombs' test).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicine, including any medicine you take without prescription.

When taken concurrently, amoxicillin can modify the way other medicines work.

Tell your doctor if you take any of the following medicines: other antibiotics, allopurinol, oral anticoagulants (drugs that prevent the forming of the blood clots), methotrexate, oral contraceptives, digitalis glycosides, probenecid, phenylbutazone, oxiphenylbutazone, sulfasalazine. Do not discontinue or start any treatment without your doctor advice.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine if you think you might be or if you are pregnant, or if you are breast-feeding.

Amoxicillin may be administered during pregnancy.

Amoxicillin is excreted in breast milk in small quantities; usually, nursing should not be discontinued during amoxicillin treatment. However, if diarrhea, candidiasis, or rash, occur in infants, breast-feeding or drug administration should be discontinued.

Driving and using machines

Amoxicillin has no influence on the capacity to drive or use machines.

Important information about some of the ingredients of Bioxillin

Methyl parahydroxybenzoate and propyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

3. HOW TO TAKE BIOXICILLIN

Always take Bioxillin exactly as your doctor has told you. You should check with doctor or pharmacist if you are not sure.

Capsules should be swallowed whole with a glass of water. Amoxicillin capsules should be administered during meals or with small amount of food. Do not crush, chew, or open the capsules.

The treatment should be continued another 2 to 3 days after the disappearance of symptoms. Treatment should be performed at least 10 days in case of infections caused by beta-hemolytic streptococcus in order to eradicate the pathogens.

Adults and adolescents:

Usually, the recommended dose is of 250 - 500 mg amoxicillin every 8 hours (three times daily).

In case of severe infections, the recommended dose is 3 g amoxicillin, twice daily.

Do not take more than 6 g of amoxicillin daily.

In patients requiring prophylaxis of bacterial endocarditis: 3 g of amoxicillin, 1 hour before dental or surgical procedure, and 1.5 g of amoxicillin, 6 hours after procedure.

In infection of Chlamydia in pregnant women, the recommended dose is 500 mg amoxicillin, every 8 hours, for 7 - 10 days.

In endocervical or urethral gonococcus infections without complications, the recommended dose is 50 mg of amoxicillin per kg of bodyweight per day, single dose.

In gastritis, and in duodenal and gastric ulcer caused by Helicobacter pylori: the recommended dose is 750 mg to 1 g amoxicillin twice daily, in association with metronidazole 400 mg daily and omeprazole 40 mg daily, or 1 g amoxicillin twice daily in association with clarithromycin 500 mg daily and omeprazole 40 mg daily.

The recommended period of treatment is 7 days.

Lyme disease:

- in erythema chronicum migrans the recommended dose is 4 g of amoxicillin daily.
- if systemic symptoms caused by hematogenous dissemination of Borrelia burgdorferi occur, the recommended dose is 6 g of amoxicillin daily, in divided doses. The treatment must be continued for 15 to 21 days.

Patients with renal failure

Creatinine clearance, (ml/min)	Daily dosage	Interval between doses
10 - 30	500 mg - 1 g	12 hours
< 10	250 mg - 500 mg	12 hours

Patients undergoing hemodialysis should take an additional dose of 500 mg after procedure.

Children over 6 years of age (bodyweight >20 kg)

The recommended dose is 25 - 50 mg amoxicillin/kg daily, in 3 divided doses (every 8 hours). The dose may be increased taking into account the nature and seriousness of the infection. Treatment time depends on therapeutic effect.

Lyme disease:

- in erythema chronicum migrans the recommended dose is 50 mg of amoxicillin per kg of bodyweight per day.
- if systemic symptoms caused by hematogenous dissemination of *Borrelia burgdorferi* occur, the recommended dose is 6 g of amoxicillin daily, in divided doses. The treatment must be continued for 15 to 21 days.

Children under 6 years of age (bodyweight <20 kg)

Pharmaceutical forms should be used in accordance with the children's age.

Always follow your doctor's schedule of drug administration, even if you feel better; symptoms may improve before your infection is completely cured.

If you take more Bioxicillin than you should

Using more of any medicine may cause serious consequences. If you have any doubts, please tell your doctor or pharmacist. The symptoms that may occur: nausea, vomiting and diarrhea, neuropsychiatric disorder.

If you forget to take Bioxicillin

If you forget to take a dose, you may take it as soon as you remember, following the treatment schedule prescribed by your doctor. Do not take a double dose to make up for forgotten individual doses.

If you stop taking Bioxicillin

You must take Bioxicillin following the treatment schedule prescribed by your doctor.

Premature discontinuation of treatment may cause infection relapse.

If you have additional questions regarding this medicine, please ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Bioxicillin can cause side effects, although not everybody gets them.

Investigations

Very rare (affects less than 1 in 10000 patients treated): the prolongation of bleeding time and prothrombin time.

Blood and lymphatic system disorders

Very rare (affects less than 1 in 10000 patients treated): reduction of number of white blood cells (that gets back on normal values after the treatment end), reduction of number of thrombocytes (that gets back on normal values after the treatment end), severe neutropenia, agranulocytosis, hemolytic anemia.

Nervous system disorders

Very rare (affects less than 1 in 10000 patients): hyperkinesias (involuntary movements), dizziness, and convulsions. Convulsions may occur in patients with renal failure or who have taken high doses of amoxicillin.

Gastrointestinal disorders

Common (affects more than 1 in 100 patients and less than 1 in 10 patients): nausea and diarrhea;

Rare (affects more than 1 in 10000 patients and less than 1 in 1000 patients): vomiting;

Very rare (affects less than 1 in 10000 patients): cutaneous candidiasis, colitis associated to the treatment (including pseudomembranous and ulceronecrotic colitis).

Discoloring of tooth enamel may occur in children (when suspensions are administered).

Usually, discoloring of tooth enamel may be removed by tooth brushing.

Renal and urinary disorders

Very rare (affects less than 1 in 10000 patients): acute interstitial nephritis (kidney inflammation) and crystalluria.

Skin and subcutaneous tissue disorders

Common (affects more than 1 in 100 patients and less than 1 in 10 patients): allergic/non-allergic maculopapular eruption;

Rare (affects more than 1 in 10000 patients and less than 1 in 1000 patients): itching, urticaria;

Very rare (affects less than 1 in 10000 patients): polymorphic erythema, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous and exfoliative dermatitis, acute generalized exanthematous pustulosis.

Immune system disorders

Very rare (affects less than 1 in 10000 patients): severe hypersensitivity reactions, including angioneurotic edema (swelling of the face, lips, mouth or neck), anaphylaxis, serum sickness, hypersensitivity vasculitis and anaphylactic shock.

If allergic reactions occur, the treatment should be discontinued.

Hepatobiliary disorders

Very rare (affects less than 1 in 10000 patients): increase of the serum values of hepatic transaminases; hepatitis (liver inflammation) and cholestatic jaundice.

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.

5. HOW TO STORE BIOXICILLIN

Keep out of the reach and sight of the children.

Store in the original package, at temperatures below 25°C.

Do not use Bioxicillin after the expiry date printed on the package after EXP. The expiry date refers to the last day of that month.

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. FURTHER INFORMATION

What Bioxicillin contains

• The active substance is amoxicillin 500 mg (as amoxicillin trihydrate).

• The other ingredients are:

Capsule content: talc, magnesium stearate.

Capsule shell: titanium dioxide (E171), gelatin; capsule cap: titanium dioxide (E171), gelatin, quinoline yellow (E104), Allura Red AC (E129), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216).

What Bioxicillin looks like and contents of the pack

Bioxicillin 500 mg, capsules are capsules with red opaque cap and white opaque body, containing white to almost white granulated powder.

Contents of the pack: Outer carton with 1 or 100 PVC/Al blisters of 10 capsules each.

The holder of trademark and Marketing Authorization is

"BioActiveT, United Kingdom."

BioActiveT