ANNEX IIIB

PACKAGE LEAFLET: INFORMATION FOR THE USER

Name of the medicinal product

BACTOX 125 mg / 5 ml, powder for oral suspension in vial

Amoxicillin

Text box

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 illnesses 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 BACTOX 125 mg/5 ml, powder for oral suspension in vial IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group : Broad-spectrum penicillins – ATC code : J01CA04

What is BACTOX?

BACTOX is an antibiotic. The active substance is amoxicillin. It belongs to a group of medicines called “penicillins”.

What is BACTOX used for?

BACTOX is used to treat infections caused by bacteria in various parts of the body.

BACTOX can also be used in combination with other medicines to treat stomach ulcers.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BACTOX 125 mg/5 ml, powder for oral suspension in vial

Do not take BACTOX 125 mg/5 ml, powder for oral suspension in vial:

- 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 an antibiotic. This may include a skin rash or swelling of the face or throat.
- In case of phenylketonuria (hereditary disease detected at birth) due to the presence of aspartame.

Do not take BACTOX if you are in one of the situations mentioned above. If you have any doubts, ask your doctor or pharmacist for advice before taking BACTOX.

Warnings and precautions

Talk to your doctor or pharmacist before taking BACTOX 125 mg/5 ml, powder for oral suspension in vial, if you:

- suffer with infectious mononucleosis (fever, sore throat, swollen glands and extreme fatigue);
- have kidney problems;
- do not urinate regularly.

If you have any doubts, ask your doctor or pharmacist for advice before taking BACTOX.

Blood and urine tests

If you need:

- urine (blood glucose) or blood tests to explore the function of your liver,
- œstriol testing (used during pregnancy to check that the baby is developing normally).

Tell your doctor or pharmacist if you are taking BACTOX. In fact, BACTOX may affect the results of these tests.

Children

Not applicable.

Other medicines and BACTOX 125 mg/5 ml, powder for oral suspension in vial

Tell your doctor or pharmacist if you are taking, have recently taken or might take any others medicines.

- If you are taking allopurinol (used in the treatment of gout) with BACTOX, there is a higher risk of an allergic skin rash.
- If you are taking probenecid (used in the treatment of gout), your doctor may decide to adjust your dose of BACTOX.
- If you are taking blood thinning medicines (such as warfarin), you may need to have additional blood tests.
- If you are taking other antibiotics (such as tetracyclines), BACTOX may be less effective.
- If you are taking methotrexate (used in the treatment of cancer and severe psoriasis), BACTOX may result in increased side effects.

BACTOX 125 mg/5 ml, powder for oral suspension in vial with food

Not applicable.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

BACTOX can cause side effects (such as allergic reactions, dizziness and seizures) that may impair your ability to drive.

Do not drive or use any machines if you are feeling unwell.

BACTOX 125 mg/5 ml, powder for oral suspension in vial contains aspartame, sodium, maltodextrin and sodium benzoate

Aspartame (E951) is a source of phenylalanine. This may be harmful for patients with a disease called “phenylketonuria”.

This medicine contains 6,26 mg of sodium per measuring-spoon. It should be taken into account for patients who have strict low salt diet.

Maltodextrin is absorbed as glucose. If your doctor has told you that you have an intolerance to certain sugars, contact him or her before using this medicine.

Due to the presence of sodium benzoate (E211), this medicine can cause irritation of the skin, eyes and mucous membranes and increase the risk of jaundice (yellowing of the skin and eyes) in newborns.

3. HOW TO TAKE BACTOX 125 mg/5 ml, powder for oral suspension in vial

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Shake the vial thoroughly before each use.
- Use the measuring-spoon supplied with the vial.
- Divide the doses regularly throughout the day; doses should be taken at intervals of at least 4 hours.

Usual dosage:

Children weighing less than 40 kg

All doses are determined according to the weight of the child in kilograms.

- Your doctor will tell you what dose of BACTOX you must give to your baby or child.
- The usual dose is between 40 mg to 90 mg per kilogram of body weight per day, given in two or three doses.
- The maximum recommended dose is 100 mg per kilogram of body weight per day.

Adults, elderly patients and children weighing 40 kg or more

This suspension is not usually prescribed in adults and children weighing more than 40 kg. Ask your doctor or pharmacist for advice.

Kidney problems

If you have kidney problems, the dose may be reduced in comparison to the usual dose.

Method and route of administration

Oral route.

For how long should you take BACTOX 125 mg/5 ml, powder for oral suspension in vial?

- You must continue taking BACTOX for as long as they are prescribed by your doctor, even if you feel better. Every dose is important to fight against infection. If some bacteria survives, they may be the cause of a recurrence of the infection.
- Once you have finished your treatment, consult your doctor again if your symptoms persist.

Mycoses (yeast infections occurring in moist areas of the body that may cause pain, itching and white discharge) can develop if BACTOX is used over a long period. If this is the case with you, inform your doctor.

If you are taking BACTOX over a long period, your doctor may perform additional tests to check whether your kidneys, liver and blood function normally.

If you take more BACTOX 125 mg/5 ml, powder for oral suspension in vial than you should

If you have taken more BACTOX than you should, this may result in stomach aches (nausea, vomiting or diarrhoea) or the formation of crystals in your urine, which causes disorders or pain when urinating.

If this occurs, consult your doctor as soon as possible. Bring the medicine to show it to your doctor.

If you forget to take BACTOX 125 mg/5 ml, powder for oral suspension in vial

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

If you stop taking BACTOX 125 mg/5 ml, powder for oral suspension in vial

Not applicable.

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 BACTOX and immediately consult a doctor if you have any of these serious side effects listed below. You may need urgent medical treatment.

Very rare side effects (may affect up to 1 in 10,000 people):

- Allergic reactions; symptoms may include: itching or skin rashes, swelling of the face, lips, tongue, body or difficulty breathing. These reactions may be severe and sometimes fatal.
- Skin rashes or pin-shaped red spots under the skin, bruising. This is caused by inflammation of the blood vessel walls due to an allergic reaction. These symptoms can be accompanied by joint pain (arthritis) and kidney problems.
- A delayed allergic reaction may usually occur 7 to 12 days after taking BACTOX; symptoms include: skin rash, fever, joint pain and swelling of the lymph nodes, especially in the underarms.

- Skin reaction known as erythema multiforme, manifested by the following symptoms: reddish or purplish patches on the skin with itching, particularly on the palms of the hands and soles of the feet, raised concentric lesions on the skin, sensitivity in the mouth, eyes and genital mucosa. This reaction may cause fever and severe fatigue.
- Other severe skin reactions, can include : changes in skin coulour, 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, sore throat or other signs of infection, frequent bruising. These side effects may be a sign of a blood cell problem.
- A Jarisch-Herxheimer reaction may occur during treatment for Lyme disease with BACTOX, which can result in fever, chills, headaches, muscle pains and skin rash.
- A Kounis syndrome characterized by chest pain that may radiate towards left shoulder and jawbone, allergic origin.
- Acute inflammation of protective membranes enveloping the brain and spinal-cord that may induce heavy headaches, reversible and non-infectious, it is called aseptic meningitis.
- Inflammation of the large intestine (colon), accompanied by diarrhoea (sometimes accompanied by bleeding), pain and fever.
- Serious side effects in the liver may occur. They are primarily observed in persons treated over a long period, in men and in elderly patients. You must consult your doctor immediately in the following cases:
    - severe diarrhoea with presence of blood;
    - appearance of blisters, redness or bruising on the skin;
    - dark urine or discoloured stools;
    - yellowing of your skin or the whites of your eyes (jaundice). See also the information below on anaemia, which can lead to jaundice.

These reactions may occur whilst taking the medicine or for several weeks after it has been discontinued.

If you have one of the reactions above, stop taking this medicine and consult your doctor immediately.

Skin reactions may sometimes be less severe:

- Skin rashes (round pink or red spots) with moderate itching, raised concentric lesions on the forearms, legs, palms of the hands and soles of the feet. These events are uncommon (may affect up to 1 in 100 people).

If one of these symptoms appears, consult your doctor because you must stop taking BACTOX.

Other possible side effects are:

Common (may affect up to 1 in 10 people)

- Skin rashes.
- Nauseas.
- Diarrhoeas.

Uncommon (may affect up to 1 in 100 people)

- Vomiting.

Very rare (may affect up to 1 in 10,000 people)

- Mycosis (yeast infection that develops in the vagina, mouth or skin folds); you can ask your doctor or pharmacist for an antifungal treatment.
- Kidney problems.
- Seizures, particularly in patients taking high doses or with kidney problems.
- Dizziness.
- Hyperactivity.
- Crystals in the urine, which causes disorders, discomfort or difficulties urinating. Make sure to drink plenty of fluids to reduce these risks.
- Spots may appear on the teeth, which is usually reversible with brushing (reported in children).
- The tongue may take on a yellow, brown or black colour, and may seem to be covered in hair.

- Excessive breakdown of red blood cells causing a type of anaemia. The symptoms include: fatigue, headaches, shortness of breath, dizziness, pallor, yellowing of the skin and whites of the eyes.
- Low number of white blood cells.
- Low number of cells involved in blood clotting.
- Blood clotting may be slowed down. You may observe this in nosebleeds or cuts.

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 national reporting system: Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM) and the network of Regional Pharmacovigilance Centres - Website: www.signalement-sante.gouv.fr.

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

5. HOW TO STORE BACTOX 125 mg/5 ml, powder for oral suspension in vial

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the vial label. The expiry date refers to the last day of that month.

Store at a temperature below 25°C.

Once reconstituted, the suspension must be stored in a refrigerator (at 2°C to 8°C) and used within 14 days.

Do not throw away any medicine 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 BACTOX 125 mg/5 ml, powder for oral suspension in vial contains

- The active substance is:

Amoxicillin ..... 125.00 mg

As amoxicillin trihydrate

For a 5 ml measuring-spoon of reconstituted suspension.

- The other ingredients are:

Citric acid anhydrous, trisodium citrate (anhydrous), sodium benzoate, talc, guar, orange flavouring, lemon flavouring, peach-apricot flavouring, aspartame, silicon dioxide.

What BACTOX 125 mg/5 ml, powder for oral suspension in viallooks like and contents of the pack

This medicine comes in the form of a powder for oral suspension.

Vial containing 5,1 g of powder corresponding to 60 ml of reconstituted oral suspension (12 measuring-spoons of 5 ml).

Marketing authorisation holder

LABORATOIRE INNOTECH INTERNATIONAL
22 AVENUE ARISTIDE BRIAND
94110 ARCUEIL

Manufacturer

INNOTHERA CHOUZY
RUE RENE CHANTEREAU, CHOUZY-SUR-CISSE
41150 VALLOIRE-SUR-CISSE

Names of the medicinal product in the Member States of the EEA

Not applicable.

This leaflet was last revised in:

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Other

Detailed information on this medicine is available on the website of ANSM (France).

ADVICE / SANITARY EDUCATION

Antibiotic are efficient in fighting against infections caused by bacteria. They are not efficient against infections caused by viruses.

Sometimes, an infection is due to bacteria that does not respond to antibiotic treatment. One of the most common reasons is that the bacteria which causes the infection is resistant to the antibiotic that is taken. This means that the bacteria may survive and even multiply despite the antibiotic.

The bacteria may become resistant to antibiotics for several reasons. The cautious use of antibiotics may reduce the risk of the bacteria becoming resistant to antibiotics.

When your doctor prescribes an antibiotic treatment for you, this is intended to treat your current condition. Carefully following this advice will prevent the emergence of resistant bacteria that could stop the activity of the antibiotic.

1. It is very important to follow the antibiotic dose, the time it is to be taken and the treatment duration. Read the instructions on the package leaflet. If you do not understand something, ask your doctor or pharmacist to explain it to you.

2. You must not take an antibiotic unless it has been specifically prescribed to you. You must only use it to treat the infection for which it has been prescribed for you.

3. You must not take antibiotics that have been prescribed to other persons, even if they have an infection similar to yours.

4. You must not give antibiotics that you have been prescribed to any other person.

5. If you have any remaining antibiotics at the end of your treatment prescribed by your doctor, you must return them to your pharmacist to be properly disposed of.

Instructions for the reconstitution

Check that the sealing cap is intact before use.

To open press and turn the cap.

Turn over and shake the vial to detach the powder.

Fill the vial up to the line with non-carbonated mineral water.

Stir until the liquid is homogeneous. If necessary, add more water up to the line and stir.

Shake the vial well before each use.

Use the measuring spoon provided with the vial to measure the prescribed dose. Fill the measuring spoon up to the edge. Wash the measuring spoon after each use.