

Ibiamox®

*Amoxicillin 250 mg, 500 mg, 1000 mg
Powder for Injection*

What is in this leaflet

Please read this leaflet carefully before you start using Ibiamox.

This leaflet answers some common questions about Ibiamox. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Ibiamox against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Ibiamox is used for

Ibiamox is used to treat a range of bacterial infections in adults and children.

Ibiamox may be used in:

- ear, nose and throat infections
- lung infections and airway infections
- stomach and intestines infection
- skin and soft tissue infections
- infections of the urinary system and reproductive organs
- other infections including Lyme Disease (infection spread through ticks)
- prevention of heart's inner lining inflammation as a result of bacteria

entering the blood during procedures such as dental extraction.

Ibiamox belongs to a group of medicines called beta-lactam antibiotics. It works by killing the bacteria which causes the infection.

Your doctor may have prescribed Ibiamox for another reason.

Ask your doctor if you have any questions about why Ibiamox has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use Ibiamox

When you must not take it

Do not take Ibiamox if you have an allergy to:

- any medicine containing amoxicillin or a class of medicines called penicillins and cephalosporins
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing
- shortness of breath
- swelling of the face, tongue, lips, or other parts of the body
- hives on the skin, rash, or itching.

Do not use Ibiamox if:

- you are allergic to amoxicillin, penicillins and cephalosporins

Caution should be exercised if you are pregnant.

The safety of use in human pregnancy has not been established. Your doctor will discuss the potential benefits and risks of using Ibiamox during pregnancy.

Caution should be exercised if you are or intend to breastfeed.

Very little quantities of amoxicillin pass into the breast milk and there is a possibility that your baby may be affected.

Do not use Ibiamox after the expiry date (EXP) printed on the pack.

Do not use Ibiamox if the packaging is torn or shows signs of tempering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using Ibiamox, talk to your doctor.

Before you start to use it

Tell your doctor if:

- 1. you have allergies to:**
 - an antibiotic in the past
- 2. you have, or have had, the following medical conditions:**
 - kidney problems
 - decreased urine
 - a blood disorder
- 3. you are pregnant or intend to become pregnant.**

Your doctor can discuss with you the risks and benefits involved.
- 4. you are breastfeeding or plan to breastfeed.**

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are on a sodium restricted diet.

During prolonged therapy, periodic tests to assess your kidney, liver and blood functions should be carried out.

Tell your doctor if you suspect you have a superinfection. This is when a new infection occurs after having a pre-existing infection. Ibiamox should be discontinued and substituted in this case.

If you have not told your doctor about any of the above, tell them before you start using Ibiamox.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Ibiamox.

Ibiamox may interfere with some medicines. These include:

- probenecid
- allopurinol
- other antibiotics, e.g. erythromycin
- medicines used to prevent blood clots, including warfarin
- methotrexate
- oestrogen containing oral contraceptives
- some diagnostic tests such as glucose in urine.

These medicines may be affected by Ibiamox, or may affect how well it works. You may need different amounts of your medicine, or you may need to use different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Ibiamox.

How to use Ibiamox

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information in this leaflet.

How much to take

Ibiamox will be administered as directed under the supervision of a doctor or nurse. You will not be expected to give yourself this medicine.

The usual intravenous dose is:

- adults and children over 40 kg: 750 mg to 6 g daily in divided doses
- children under 40 kg: 20 to 200 mg/kg/day in divided doses

The usual intramuscular dose is:

- adults and children over 40 kg: 4 g daily in divided doses
- children under 40 kg: 120 mg/kg/day as 2 to 6 equally divided doses.

How to use it

Your doctor or nurse will inject the necessary dose of Ibiamox. It may be given by infusion, or via a drip tube or injection directly into the vein. It may also be injected into a muscle.

How long to use it

Ibiamox should be administered for as long as it is recommended by your doctor. The length of treatment will be decided by your doctor.

While you are using Ibiamox

Things you must do

Tell your doctor or nurse if you develop nausea, vomiting or diarrhoea when you are receiving Ibiamox.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are using Ibiamox.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine. It may affect other medicines used during surgery.

If you become pregnant while using this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are using this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not give Ibiamox to anyone else, even if they have the same condition as you.

Do not use Ibiamox to treat any other complaints unless your doctor tells you to.

Do not stop using Ibiamox, or lower the dosage, without checking with your doctor. If you suddenly stop using Ibiamox, your condition may worsen or you may have unwanted side effects.

Things to be careful of

Be careful driving or operating machinery until you know how Ibiamox affects you.

Be careful when drinking alcohol while you are taking this medicine.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have been given too much Ibiamox.

Do this even if there are no signs of discomfort or poisoning. Symptoms of an overdose may include nausea, vomiting and diarrhoea. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Ibiamox.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

You may need medical treatment if you get some of the adverse effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- diarrhoea, indigestion, feeling sick or being sick
- soreness of the mouth or tongue
- overgrowth of yeast infections (thrush)

Tell your doctor as soon as possible if you notice any of the following symptoms:

- headache, fever, tiredness, hot flashes or oral ulcers (these could be symptoms of decreased white blood cells)
- dizziness
- abdominal pain, loss of appetite, cramping, bloating
- swelling of the skin
- itching skin and joint aches
- pain around the injection site
- unusual bleeding or bruising
- yellowing of the skin or eyes
- severe diarrhoea
- decreased urine, blood or crystal in urine, drowsiness and weight gain
- difficulty or pain on passing urine
- 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))

If any of the following happen, stop taking Ibiamox and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- wheezing, swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, hives, fainting (these could be symptoms of an severe allergic reaction)
- convulsions or seizure

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice any other effects or if you feel unwell. Ask your doctor or pharmacist if you have any questions.

After using Ibiamox

Storage

Keep all preparations in a cool dry place where the temperature stays below 25°C. Protect from moisture and light.

Do not store Ibiamox or any medicine in the bathroom or near a sink. Do not leave it in the car or on a windowsill. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

Product description

What it looks like

Ibiamox 250 mg, 500 mg, 1000 mg Powder for injection is a white to cream powder packed in clear glass vials for reconstitution.

Ingredients

Active ingredient(s):

- amoxicillin, as amoxicillin sodium

Sponsor details

Ibiamox is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

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30 May 2018

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