

Package leaflet: Information for the user

Oramox 125mg / 5ml Powder for Oral Suspension Oramox 250mg / 5ml Powder for Oral Suspension

Amoxicillin

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 (or for your child) 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 Oramox is and what it is used for
2. What you need to know before you take Oramox
3. How to take Oramox
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1. What Oramox is and what it is used for

What Oramox is

Oramox is an antibiotic. The active ingredient is amoxicillin trihydrate. This belongs to a group of medicines called 'penicillins'.

What Oramox is used for

Oramox is used to treat infections caused by bacteria in different parts of the body. Oramox may also be used in combination with other medicines to treat stomach ulcers.

2. What you need to know before you take Oramox

Do not take Oramox

- 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 any antibiotic. This can include a skin rash or swelling of the face or throat.

Do not take Oramox if any of the above apply. If you are not sure, talk to your doctor or pharmacist before taking Oramox

Warnings and Precautions

Talk to your doctor or pharmacist before taking Oramox if you:

- have glandular fever (fever, sore throat, swollen glands and extreme tiredness)
- have kidney problems
- are not urinating regularly

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Oramox.

Blood and urine tests

If you are having:

- Urine tests (glucose) or blood tests for liver function
- Oestriol tests (used during pregnancy to check the baby is developing normally)

Tell your doctor or pharmacist that you are taking Oramox. This is because Oramox can affect the results of these tests.

Other medicines and Oramox

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

- If you are taking allopurinol (used for gout) with Oramox it may be more likely that you will have an allergic skin reaction
- If you are taking probenecid (used for gout), concomitant use of probenecid may reduce the excretion of Oramox and is not recommended.
- If you are taking medicines to help stop blood clots (such as warfarin), you may need extra blood tests
- If you are taking other antibiotics (such as tetracycline) Oramox may be less effective
- If you are taking methotrexate (used for the treatment of cancer and severe psoriasis) Oramox may reduce the excretion of methotrexate causing a potential increase in side effect

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

Oramox can have side effects and the symptoms (such as allergic reactions, dizziness and convulsions) may make you unfit to drive.

Do not drive or operate machinery unless you are feeling well.

Oramox contains sucrose, sodium and sodium benzoate

Oramox contains 2.7g of sucrose per 5ml dose.

- This should be taken into account in patients with diabetes mellitus.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Oramox 125mg/5ml Oral Suspension contains 3.79 mg of sodium (main component of cooking/table salt) in each 5 ml dose. This is equivalent to 0.19% of the recommended maximum daily dietary intake of sodium for an adult.

Oramox 250mg/5ml Oral Suspension contains 6.47 mg of sodium (main component of cooking/table salt) in each 5 ml dose. This is equivalent to 0.32% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 4.82 mg sodium benzoate in each 5 ml dose which is equivalent to 0.964 mg/ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take Oramox

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 bottle well before each dose
- Space the doses evenly during the day, at least 4 hours apart.

The usual dose is:

Children weighing less than 40kg

All doses are worked out depending on your child's body weight in kilograms.

- Your doctor will advise you how much Oramox you should give to your baby or child based on their specific infection
- The usual dose is 40mg – 90mg for each kilogram of body weight a day, given in two or three divided doses.
- The maximum recommended dose is 100 mg for each kilogram of body weight a day.

Adults, elderly patients and children weighing 40kg or more

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

Kidney problems

If you have kidney problems the dose might be lower than the usual dose.

If you take more Oramox than you should

If you have taken too much Oramox, signs might be an upset stomach (feeling sick, being sick or diarrhoea) or crystals in the urine, which may be seen as cloudy urine, or problems urinating. Talk to your doctor as soon as possible. Take the medicine to show the doctor.

If you forget to take Oramox

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

How long should you take Oramox for?

- Keep taking Oramox for as long as your doctor has told you to, 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.
- Once you finish treatment, if you still feel unwell you should go back to see the doctor

Thrush (a yeast infection of moist areas of the body which can cause soreness, itching and white discharge) may develop if Oramox is used for a long time. If this occurs tell your doctor.

If you take Oramox for a long time, your doctor may perform additional tests to check your kidneys, liver and blood are working normally.

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

- allergic reactions, the signs may include: skin itching or rash, swelling of the face, lips, tongue 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 Oramox, 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 genitals. 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
- 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, a sore throat or other signs of an infection, or if you bruise easily. 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. 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
 - blisters, redness or bruising of the skin
 - darker urine or paler stools
 - 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 happens 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 (may affect up to 1 in 100 people).

If you have any of these talk to your doctor as Oramox will need to be stopped.

The other possible side effects are:

Common (may affect up to 1 in 10 people)

- skin rash
- feeling sick (nausea)
- diarrhoea

Uncommon (may affect up to 1 in 100 people)

- being sick (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 doctor or pharmacist.
- kidney problems
- fits (convulsions), seen in patients on high doses or with kidney problems
- dizziness
- hyperactivity
- 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 type of anaemia. Signs include: tiredness, headaches, shortness of breath, dizziness, looking pale and yellowing of the skin and the whites of the eyes
- low number of white blood cells
- low number of cells involved with blood clotting
- the blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or cut yourself.

Frequency not known (frequency cannot be estimated from available data)

- *Jarisch-Herxheimer reaction* (possible flu-like symptoms, headache, joint and muscle pain, body aches, sore throat, generally unwell, sweating, chills, nausea)
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)
- Drug-induced enterocolitis syndrome (DIES): DIES has been reported mainly in children receiving amoxicillin. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after drug intake). Further symptoms could comprise abdominal pain, lethargy, diarrhoea, and low blood pressure.
- Crystals in urine leading to acute renal injury.

- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- Inflammation of the membranes that surround the brain and spinal cord (aseptic meningitis)

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:

HPRA Pharmacovigilance,
Earlsfort Terrace,
IRL - Dublin 2,
Tel: +353 1 6764971;
Fax: +353 1 6762517;
Website: www.hpra.ie,
e-mail: medsafety@hpra.ie.

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

5. How to store Oramox

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 label and carton. The expiry date refers to the last day of that month.

Dry powder:

Do not store above 25°C.

Store in the original container. Keep the bottle tightly closed.

Reconstituted suspension

Store in the original container. Store for 7 days at 2°C - 8°C in a refrigerator.

Do not use this medicine if there are visible signs of deterioration.

Do not throw away any medicines 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 Oramox contains

- The active substance in each suspension is 125mg or 250mg amoxicillin (as amoxicillin trihydrate).
- The other ingredients are Sodium benzoate (E211), Disodium edetate, Sodium citrate anhydrous, Lemon flavour powder, Quinoline yellow (E104) and Sucrose. (See Section 2, ‘Oramox contains sucrose, sodium and sodium benzoate’).

What Oramox looks like and contents of the pack

Your medicine comes in a bottle containing a pale yellow powder with the odour and flavour of lemon. The 125mg/5ml strength is available in bottles containing either 60ml or 100ml of suspension as prepared by the pharmacist. The 250mg/5ml strength is available in bottles containing 100ml of suspension as prepared by the pharmacist. A spoon may be supplied with packs of this product.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Athlone Pharmaceuticals Limited, Connaught House, 1 Burlington Road, Dublin 4, Ireland.

Manufacturer:

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

PA Number: PA1418/013/001 – Oramox 125 mg/5 ml Powder for Oral Suspension

PA Number: PA1418/013/002 – Oramox 250 mg/5 ml Powder for Oral Suspension

This leaflet was last revised in September 2023.

General advice regarding the use of antibiotics

Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses.

Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic.

Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them.

When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of

resistant bacteria that could stop the antibiotic working.

1. It is very important that you take the antibiotic at the right dose, at the right times and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.
2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. If you have any antibiotic left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.