

PATIENT INFORMATION LEAFLET

Oramox 250mg Hard Capsules Oramox 500mg Hard Capsules Amoxicillin (as amoxicillin trihydrate)

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 your 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 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.

What is in this leaflet

1. What Oramox Hard Capsules are and what they are used for
2. What you need to know before you take Oramox Hard Capsules
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4. Possible side effects
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1. WHAT ORAMOX HARD CAPSULES ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Oramox 250mg Hard Capsules or Oramox 500mg Hard Capsules. Each hard capsule contains amoxicillin trihydrate equivalent to either 250mg or 500mg of amoxicillin. Amoxicillin is one of a group of antibiotics called broad spectrum antibiotics. Oramox is used to treat a variety of infections in different parts of the body caused by bacteria, including those of:

- the nose, sinuses and throat (upper respiratory tract infections)
- the ear (otitis media)
- the chest (bronchitis) and lungs (pneumonia)
- the urinary tract and the kidney (cystitis, urethritis and pyelonephritis)
- the female reproductive system including infections associated with pregnancy or caused by difficulties during childbirth (puerperal sepsis and septic miscarriage)
- the abdomen (intra-abdominal sepsis and peritonitis)
- the blood (septicaemia) or the heart (endocarditis). Your medicine can also be used following dental work or other operations to prevent bacterial endocarditis (bacterial infections of the heart) in patients who have heart conditions or artificial heart valves.
- the skin
- typhoid or paratyphoid (infections spread by food or contaminated water with symptoms of high fever and stomach upset)

Oramox may also be used to treat dental infections (abscesses) when you have a tooth removed or other dental surgery and gonorrhoea (a sexually transmitted infection)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ORAMOX HARD

CAPSULES

Do not take Oramox Hard Capsules if you:

- Have ever had a bad reaction or allergy to any penicillin-type antibiotic
- Have ever had a skin rash, swelling of the face or neck, or shortness of breath when taking any antibiotic
- Are allergic to amoxicillin or any of the other ingredients contained in this medicine (listed in section 6)

Warnings and precautions

Check with your doctor or pharmacist before taking Oramox Hard Capsules if you:

- Suffer from kidney or liver problems
- Are suffering from glandular fever
- Are pregnant or breast-feeding, or planning pregnancy or breast-feeding
- Are not passing water regularly

In newborn and premature babies, liver, kidney and blood functions should be closely monitored.

Other medicines and Oramox Hard Capsules

Check with your doctor, pharmacist or nurse 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 (medicines used to prevent blood clots e.g. warfarin and acenocoumarol)
- Medicines used to treat gout (which can be caused by the buildup of uric acid) e.g. probenecid or allopurinol
- Some other antibiotics taken at the same time (e.g. tetracyclines, chloramphenicol, sulfonamides and erythromycin) may affect the way Oramox Hard Capsules work
- The contraceptive pill (in which case you will have to take extra contraceptive measures such as using a condom)
- Methotrexate (used to treat tumours, Crohn's disease, psoriasis and rheumatoid arthritis)

Blood or urine tests

If you or your child are having urine tests e.g. for diabetes (sugar in the urine) or blood tests e.g. for liver function let the doctor know that you or your child are taking Oramox as amoxicillin can affect the results of these tests.

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

This medicine is not likely to affect your ability to drive or operate machinery.

3. HOW TO TAKE ORAMOX HARD CAPSULES

Follow all directions given to you by your doctor or pharmacist. 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.

The dose of Oramox Hard Capsules your doctor prescribes and the length of time for which you will have to take them will depend on your infection.

Oramox Hard Capsules can be taken with or without food.

Dosage

You should follow your doctor's or prescriber's directions on how to take this product.

Adults, children weighing over 40kg and older people:

The total daily dose should not exceed a total of 6g, given in divided doses.

- The usual dose of Oramox Hard Capsules is 250mg three times a day.
- For more severe infections this may be doubled to 500mg three times a day.
- High doses may be used in the following conditions:
 - Severe or recurrent chest infections: 3g twice daily
 - Simple urinary tract infections: two 3g doses with 10 to 12 hours between doses (short course)
 - Dental abscesses (infection under the gums and teeth): two 3g doses with 8 hours between doses
 - Gonorrhoea (a sexually transmitted infection): a single 3g dose
- Preventing infection during dental procedures and other surgery: 3g Oramox orally, 1 hour before procedure. A second dose may be given 6 hours later, if considered necessary

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Children weighing less than 40kg:

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

It is recommended that children (younger than 6 years of age) be given Oramox as a suspension instead of as capsules.

- Children weighing more than 40kg should receive the same as the adult dose.
- Children weighing less than 40kg who are able to swallow capsules:
 - The total daily dose should not exceed a total of 3g, given in divided doses.
 - The usual dose is 40mg – 90mg for each kilogram of body weight a day, given in two or three divided doses.

- Preventing infection during dental procedures and other surgery: 50mg amoxicillin for every kilogram of body weight given as a single dose one hour preceding the surgical procedure.
- Tonsillitis: 50mg for every kilogram of body weight per day in 2 divided doses
- Infections of the ear: Your doctor will decide the appropriate dose

Early Lyme disease (isolated erythema migrans)

50mg/kg/day in three divided doses, over 14-21 days.

If you have kidney problems

For patients with kidney problems, your doctor may prescribe a lower dose or choose a different medicine.

If you take more of your medicine than you should

If you take more medicine than you should, tell your doctor immediately or go to the nearest hospital. You should take this leaflet and any capsules 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 glucose to prevent dehydration. Contact your doctor or pharmacist for further advice.

If you forget to take your medicine

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 stop taking your medicine

Keep taking this medicine until 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 reoccur or get worse.

If you still feel unwell at the end of your course of treatment, tell your doctor.

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| <p>4. POSSIBLE SIDE EFFECTS</p> |
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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 Oramox Hard Capsules right away and tell your doctor.
- Stevens-Johnson syndrome (a serious illness, signs of which may include blistering of the skin, mouth, eyes and genitals)
- Toxic epidermal necrolysis (a serious illness, signs of which may include blistering of the skin)
- Erythema multiforme- This is a skin reaction which involves itchy reddish purple lesions on the skin, often on the limbs

- Acute generalised exanthematous pustulosis- This is a red rash with small blisters
- Hypersensitivity Vasculitis- This is a rash or pinpoint flat red round spots under the skin or bruising of the skin. This is due to inflammation of blood vessels caused by allergy.
- 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.
- Allergic skin reactions with itching e.g. ‘hives’ or ‘nettle rash’. If you start to itch or get a rash, STOP taking Oramox Hard Capsules and tell your doctor immediately.
- Severe diarrhoea possibly with bleeding (pseudomembranous colitis)
- Convulsions
- Notice your skin or the whites of your eyes turning yellow (jaundice), hepatitis (inflammation of the liver)
- Difficulty or discomfort in passing urine or having blood in the urine

The following symptoms are less serious but you may wish to discuss them with your doctor if they become troublesome or last a long time.

Tell your doctor if you notice any of the following effects:

Common side effects (may affect up to 1 in 10 people):

- Nausea (feeling sick)
- Diarrhoea

Uncommon side effects (may affect up to 1 in 100 people):

- Vomiting (being sick)

Very rare side effects (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.
- Tooth discolouration. The colour usually returns to normal with brushing.
- Blackening of the tongue
- Excessive body movements (hyperkinesia) or dizziness
- Reduction (reversible) in blood cell counts that may result in anaemia (may be characterised by feeling weak or light-headed), or a longer time taken for blood to clot, or being more susceptible to infections
- Crystalluria, forming of crystals in the urine
- Change in liver enzymes
- Urine becoming darker or faeces becoming paler
- Meningitis (signs may include stiff neck, fever and vomiting)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 HAARD CAPSULES

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

Do not store above 25°C.

Store in the original package to protect from light and moisture.

Keep the container tightly closed.

KEEP THIS MEDICINE 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. 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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What your medicine contains

Each hard capsule contains amoxicillin trihydrate equivalent to either 250mg or 500mg of anhydrous amoxicillin. The capsules also contain the following ingredients: magnesium stearate, maize starch, gelatin, erythrosine (E127), quinoline yellow (E104), titanium dioxide (E171) and red iron oxide (E172).

What your medicine looks like and contents of the pack

Oramox 250mg Hard Capsules have a scarlet cap and ivory body and are marked 'Amox 250'.

Oramox 500mg Hard Capsules have a scarlet cap and ivory body and are marked 'Amox 500'.

The 250mg strength are available in packs of 100, 500 and 1000 capsules. The 500mg strength are available in pack sizes of 100 and 500 capsules.

Not all pack sizes may be marketed.

The product is made by:

Your medicine is manufactured by Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

The marketing authorisations are also held by Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

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