

## **PATIENT INFORMATION LEAFLET**

**Oramox (Amoxicillin Oral Suspension BP) 125mg/5ml**  
**Oramox (Amoxicillin Oral Suspension BP) 250mg/5ml**  
**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 Oral Suspension is and what it is used for
2. What you need to know before you take Oramox Oral Suspension
3. How to take Oramox Oral Suspension
4. Possible side effects
5. How to store Oramox Oral Suspension
6. Contents of the pack and other information

## **1. WHAT ORAMOX ORAL SUSPENSION IS AND WHAT IT IS USED FOR**

The name of your medicine is Oramox. It is a powder for oral suspension. When prepared by the pharmacist, each bottle contains 100ml of suspension. Each 5ml spoonful of Oramox contains either 125mg or 250mg of Amoxicillin as amoxicillin trihydrate. Amoxicillin is one of a group of antibiotics called broad spectrum antibiotics. Oramox is used to kill bacteria which cause infections in your body.

Oramox can also be used to treat

- Dental infections (abscesses)
- Gonorrhoea (a sexually transmitted infection)
- Prevent bacterial infections of the heart (bacterial endocarditis) following dental work or other operations in patients who have heart conditions or artificial heart valves.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ORAMOX ORAL SUSPENSION**

### **Do not take Oramox 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 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
- Have an intolerance to some sugars or have diabetes as this medicine contains sucrose

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

### **Other medicines and Oramox**

Check with your doctor or pharmacist 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 build up 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 oral suspension works.
- 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.

### **Oramox contains sucrose**

Oramox (Amoxicillin Oral Suspension) 125mg/5ml and 250mg/5ml contain 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.
- May be harmful to the teeth (during long term use e.g. for two weeks or more)

Oramox 250mg/5ml Oral Suspension contains 77.64mg of sodium per maximum 3g dose

Oramox 125mg/5ml Oral Suspension contains 90.96mg of sodium per maximum 3g dose.

To be taken into consideration by patients on a controlled sodium diet.

## **3. HOW TO TAKE ORAMOX ORAL SUSPENSION**

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.

Oramox 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 6g in total, given in divided doses.

- The usual dose for most infections is 5ml of Oramox 250mg/5ml Oral Suspension to be taken 3 times a day.
- For more serious infections the dose may be doubled to 10ml of Oramox 250mg/5ml Oral Suspension 3 times a day.
- High doses may be given 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 gum and teeth): two 3g doses with 8 hours between doses
  - Gonorrhoea (a sexually transmitted infection): a single 3g dose
  - Preventing infection during dental procedures or other surgery: 3g Oramox orally, 1 hour before the procedure. A second dose may be given 6 hours later, if considered necessary.

#### **Use in children weighing less than 40kg:**

- **All doses are worked depending on your child's body weight in kilograms.** Children weighing more than 40kg should be given the usual adult dose
- Your doctor or pharmacist will advise you how much Oramox you should give to your child
- The total daily dose should not exceed a total of 3g, given in divided doses.
- The usual recommended dose is 40mg – 90mg for each kilogram of body weight a day, given in two or three divided doses.
- For preventing infection during dental procedures and other surgery:
  - 50mg amoxicillin/kg body weight given as a single dose one hour before the procedure
  - Tonsillitis: 50mg/kg/day in divided doses
  - Ear infections - your doctor will recommend the appropriate dose for you

#### **If you have kidney problems**

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

#### **Early Lyme disease (isolated erythema migrans)**

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

**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 medicine 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

<b>4. POSSIBLE SIDE EFFECTS</b>
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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 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 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.**

**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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRAs Pharmacovigilance,  
Earlsfort Terrace,  
IRL - Dublin 2,  
Tel: +353 1 6764971;  
Fax: +353 1 6762517;  
Website: [www.hpra.ie](http://www.hpra.ie),  
e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

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

### **5. HOW TO STORE ORAMOX ORAL SUSPENSION**

Do not use your medicine after the expiry date which is stated on the label (after abbreviation e.g. EXP.). The expiry date refers to the last day of that month.

Dry powder: Store in a dry place below 25°C. Store in the original container. Keep the bottle tightly closed.

Reconstituted suspension: Store for 7 days at 2°C-8°C in a refrigerator.

**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 5ml spoonful of Oramox (Amoxicillin Oral Suspension BP) contains either 125 mg or 250 mg of Amoxicillin as amoxicillin trihydrate. Each bottle also contains sodium benzoate (E211), disodium edetate, sodium citrate anhydrous, lemon flavour powder, quinoline yellow (E104) and sucrose.

### **What your medicine looks like and the 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 with graduations of 1.25ml, 2.5ml and 5ml measures or a spoon with a 5ml graduation may be supplied with packs of this product.

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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