

Patient Information Leaflet

SCHEDULING STATUS: **S4**

ORASIL 250 mg Capsules

ORASIL 500 mg Capsules

Amoxicillin

Sugar-free

Read all of this leaflet carefully before you start taking ORASIL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ORASIL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ORASIL is and what it is used for
2. What you need to know before you take ORASIL
3. How to take ORASIL
4. Possible side effects
5. How to store ORASIL
6. Contents of the pack and other information

1. What ORASIL is and what it is used for

ORASIL belongs to a group of antibiotic medicines called penicillins. The active ingredient is amoxicillin. ORASIL works by interfering with the growth of the bacteria that cause the infection. ORASIL is used in adults and children to treat various infections.

2. What you need to know before you take ORASIL

Do not take ORASIL:

- if you are hypersensitive (allergic) to amoxicillin, or any of the other ingredients of ORASIL.
See section 6.

- if you are hypersensitive (allergic) to penicillins or other beta lactam antibiotics (e.g. cephalosporins.)
- if you have had a serious allergic reaction to any antibiotics.
Some of the symptoms of an allergic reaction may include asthma, wheezing, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, skin rash, itching or hives.

Warnings and precautions

Take special care with ORASIL:

- if you have ever had a severe allergic reaction to any other antibiotic, especially other beta-lactam antibiotics (e.g. carbapenems or monobactams). This can include a skin rash or swelling of the face or throat.
- if you have kidney or liver problems, as you may require a lower dose.
- If you have previously had fits or are using medication for epilepsy
- If you develop a serious rash: Stevens-Johnson syndrome, urticaria or acute generalised exanthematous pustulosis (AGEP). See section 4.
- if you develop diarrhoea, with or without blood and mucus, stomach pain, fever (pseudomembranous colitis).
- if you are not passing water regularly.
- if you have blood cancer (lymphatic leukaemia)
- if you have syphilis
- if you are breastfeeding
- if you are using medication to prevent blood from clotting eg. Warfarin

If you are having:

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

Tell your doctor or pharmacist if you are taking ORASIL as it can affect the results of these tests.

Other Medicines and ORASIL

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

- If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of ORASIL.

- If you are taking allopurinol (used for gout) with ORASIL, it may be more likely that you will have an allergic skin reaction.
- Digoxin, a medicine used to treat heart failure.
- If you are taking other antibiotics (such as tetracycline). ORASIL may be less effective.
- If you are taking medicines to help stop blood clots (such as warfarin), you may need extra blood tests.
- If you are taking methotrexate (used for the treatment of cancer and severe psoriasis), ORASIL may cause an increase in side effects.
- If you are taking oral contraceptives (the “pill”), ORASIL can interfere with the medicine’s ability to work effectively. You are advised to take supplementary non-hormonal contraceptive measures e.g. condoms

Pregnancy, breastfeeding and fertility

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 ORASIL.

Contraception

Concurrent use of ORASIL and oral contraceptives decreases the efficacy of the oral contraceptive. Patients are strongly advised to use an alternative or additional method of contraception while taking this medicine (see section 4.5).

Pregnancy

The safety of ORASIL in pregnancy has not been established.

Breastfeeding

Amoxicillin is excreted into breast milk in small quantities and may cause diarrhoea and fungus infection in the breast-fed infant in which case breast-feeding might have to be discontinued. ORASIL should therefore be used with caution when taken by breastfeeding women.

Driving and use of machines

ORASIL can cause side effects (such as allergic reactions, dizziness and convulsions) which may make you unfit to drive or operate machinery. Do not drive or operate machinery unless you are feeling well. It is not always possible to predict to what extent ORASIL may interfere with the daily activities of a patient. A patient should ensure that they do not engage in the above activities until they are aware of the measure to which ORASIL affects them.

3. How to take ORASIL

Do not share medicines prescribed for you with any other person.

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

Swallow the capsules whole with a glass of water.

Space the doses evenly during the day, at least 4 hours apart.

Adults and children over 40 kg:

The usual dose is 250 mg to 500 mg three times a day. Depending on the severity and type of infections, your doctor may increase your dose to a maximum dose of 6 g per day.

Children weighing less than 40 kg who are able to swallow capsules:

All doses are worked out depending on the child's body weight in kilograms. Your doctor will tell you how many capsules to give to your child. The maximum recommended dosage is 150 mg per kilogram per day in divided doses.

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

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

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

Your doctor will tell you how long your treatment with ORASIL will last. Do not stop treatment early. If you have the impression that the effect of ORASIL is too strong or too weak, tell your doctor or pharmacist.

If you take more ORASIL than you should

If you have taken too much ORASIL, you might feel nauseas, get diarrhoea and vomit. You might have difficulty passing urine and your urine can look cloudy. You might start having fits.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ORASIL

If you miss a dose, take it as soon as you remember and continue as usual.

If it is almost time for your next dose, skip the missed dose and continue as usual.

Do not take a double dose to make up for a forgotten dose.

If you stop taking ORASIL

Keep taking ORASIL until you finish the course of treatment, 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.

4. Possible side effects

ORASIL can have side effects.

Not all side effects reported for ORASIL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ORASIL, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking ORASIL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- allergic reactions, the signs may include; skin itching or rash, swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- fainting;
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).

These are all very serious side effects. If you have them, you may have had a serious reaction to ORASIL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals, 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 (Stevens-Johnson syndrome). A more severe form, causing extensive peeling of the skin (more than 30 % of the body surface - toxic epidermal necrolysis)

- a widespread red skin rash with small pus-containing blisters (bullous exfoliative dermatitis)
- a red, scaly rash with bumps under the skin and blisters (exanthemous pustulosis)
- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease).
- a skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge – erythema multiforme);
- ‘Hive-like’ raised swollen areas on the skin, especially on the palms of the hands or soles of the feet, tender areas on the surfaces of the mouth, eyes and genitals. You may have a fever and be very tired (urticaria)
- 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 (acute generalised exanthematous pustulosis (AGEP))
- 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.
- the Jarisch-Herxheimer reaction which occurs during treatment with ORASIL for Lyme disease and causes fever, chills, headache, muscle pain and skin rash.
- DIES (Drug-induced enterocolitis syndrome) 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 medicine intake). Further symptoms could comprise abdominal pain, lethargy, diarrhoea, and low blood pressure.
- 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).

These can happen when taking the medicine or for up to several weeks after.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Skin rash,
- Urticaria
- Feeling sick (nausea), vomiting, indigestion,
- Abdominal pain
- Diarrhoea
- Headache
- Tiredness and hot flushes
- Abnormal taste
- Vaginitis

Less frequent side effects:

- thrush (*Candida* - a yeast infection of the vagina, mouth or skin folds)
- kidney problems
- fits (convulsions), seen in patients on high doses or with kidney problems
- dizziness
- hyperactivity
- restlessness (hyperkinesia)
- crystals in the urine, which may be seen as cloudy urine, or difficulty or discomfort in passing urine. Make sure you drink plenty of fluids to reduce the chance of these symptoms
- the tongue may change to yellow, brown or black and it may have a hairy appearance
- colitis
- gastritis, stomatitis, glossitis
- tooth discolouration
- 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of ORASIL.

5. How to store ORASIL

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep in a cool, dry place.

This medicinal product does not require any special storage conditions.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Content of the pack and other information

What ORASIL contains

ORASIL 250: Each capsule contains amoxicillin trihydrate equivalent to amoxicillin 250 mg.

ORASIL 500: Each capsule contains amoxicillin trihydrate equivalent to amoxicillin 500 mg.

The other ingredients are microcrystalline cellulose, magnesium stearate, carmoisine, iron oxide yellow, titanium dioxide, purified water, gelatine, shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, black iron oxide and potassium hydroxide.

What ORASIL looks like and content of pack

ORASIL 250: Maroon / yellow, size "1" hard gelatine capsule filled with white to off white granular powder and imprinted with "A" on maroon cap and "85" on yellow body with black ink.

It is packaged in HDPE containers containing 500 capsules.

ORASIL 500: Maroon / yellow, size "0EL" hard gelatine capsule filled with white to off white granular

powder and imprinted with "A" on maroon cap and "86" on yellow body with black ink.

It is packaged in HDPE containers containing 100 capsules.

Holder of Certificate of Registration

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