PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ORITAXIM 500 sterile powder for injection

ORITAXIM 1000 sterile powder for injection

Cefotaxime sodium

Sugar free

Contains sodium:

ORITAXIM 500: Each gram of cefotaxime contains approximately 24,12 mg of sodium

ORITAXIM 1 000: Each gram of cefotaxime contains approximately 48,25 mg of sodium

Read all of this leaflet carefully before you are given ORITAXIM

- 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.
- ORITAXIM 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 ORITAXIM is and what it is used for

ORITAXIM contains cefotaxime. Cefotaxime belongs to a group of medicines known as cephalosporin antibiotics. Cefotaxime is an antibiotic used to treat infections in different parts of the body caused by bacteria.

ORITAXIM is used for the treatment of the following common infections:

- Genito-urinary tract [infection of bladder, kidney and reproductive tract (gonorrhoea)]
- Skin and soft tissue (infections of the skin like cellulitis, impetigo, furunculosis, abscess)
- Respiratory tract (infection of lungs and airways such as sinusitis, pneumonia, pharyngitis, follicular tonsillitis, scarlet fever, bronchitis, septic sore throat)
- Ear (otitis media)
- Gastro-intestinal tract (infections of stomach and bowel such as enteritis, dysentery)
- Meningitis in children (infections around the brain or spinal cord)
- Sepsis (whole-body inflammation caused by severe infection)

Cefotaxime works by killing bacteria that are causing your infection.

2. What you need to know before you you are given ORITAXIM

ORITAXIM should not be administered to you:

- if you are hypersensitive (allergic) to cefotaxime or to any cephalosporin antibiotics or any of the other ingredients of ORITAXIM (listed in section 6). The symptoms of an allergic reaction include rash, itching, swelling of face, lip/hands/feet or breathing difficulties.
- If you have previously had a severe allergic reaction to penicillin and any other beta-lactam antibiotic.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you have previously had an allergic reaction to penicillin or other antibiotics of this type. Not all people who are allergic to penicillin are also allergic to cephalosporins. Before you are given ORITAXIM your doctor should check whether you have previously had an allergic reaction to such medicines.
- if you have kidney problems. You will be carefully monitored throughout your treatment.
- if you are on a low salt diet, your doctor should make sure you are not receiving too much salt by way of ORITAXIM injections.
- if you are being treated for longer than 7 - 10 days, your doctor should monitor your blood with blood counts.
- if you are going to have a blood transfusion, make sure that the doctor who organises your transfusion knows that you are receiving ORITAXIM.
- If you are taking aminoglycosides such as streptomycin and gentamicin. Your kidney function will be carefully monitored.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with cefotaxime treatment. Stop using ORITAXIM and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

You should be kept under observation in case you develop another infection, particularly colitis (infection of the lower bowel), while you are being treated with ORITAXIM.

Other medicines and ORITAXIM

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

Please check with your doctor if you are taking any of the following:

- Penicillin antibiotics such as mezlocillin and azlocillin.
- Aminoglycoside antibiotics such as streptomycin, neomycin or gentamicin.
- Furosemide or other strong diuretics, used to get rid of excess water from the body.
- Probenecid, used to prevent gout.

If you are diabetic, you may get false positive results with urine glucose tests, such as Clinitest.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking/using/receiving ORITAXIM.

The safety of ORITAXIM in pregnancy and breastfeeding have not been established.

Driving and using machines

It is not always possible to predict to what extent ORITAXIM may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ORITAXIM affects them.

ORITAXIM may cause dizziness. If you are affected, you should not drive or operate machinery.

ORITAXIM contains sodium

ORITAXIM 500 and 1 000 contain 24,12 mg and 48,25 mg sodium respectively in each dosage unit. This is equivalent to 1,2 % and 2,4 % respectively of the recommended maximum daily dietary intake of sodium of an adult.

3. How ORITAXIM will be administered

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

You will not be expected to give yourself ORITAXIM. It will be given to you by a person who is qualified to do so.

Your doctor or nurse will prepare your injection by dissolving the ORITAXIM powder in a suitable fluid for injection. The mixture is usually injected intramuscularly (into a muscle) or given intravenously (into a vein) either by injection or infusion (drip).

For prevention of infections

The minimum effective dose will be 1 g ORITAXIM 30 – 90 minutes prior to surgery.

For the treatment of infections

Adults

The usual dose will depend on the type of infection that you have, where the infection is in the body and how serious the infection is. Your doctor will decide on the dose that you need.

The usual dose is 2 g dose per day in divided doses.

Your doctor may increase the dose to 3 to 4 g per day in divided doses depending on the severity of your illness.

Paediatrics

Use in infants and children:

The usual dose for children of 50- 100 mg/kg body mass per day in divided doses.

Your doctor may increase the dose up to 200 mg/kg body mass per day in divided doses depending on severity of your illness.

Neonates:

The recommended dosage regimen for neonates is as follows:

0 -7 days (1 week) of age: 50 mg/kg IV at 12 hour intervals.

7-28 days (1-4 weeks) of age: 50 mg/kg IV at 8 hour intervals

The dosages above are applicable to both premature and full-term infants.

Patients with kidney problems

Your doctor will decide the appropriate dose for you.

Your doctor will tell you how long your treatment with ORITAXIM will last. If you have the impression that the effect of ORITAXIM is too strong or too weak, tell your doctor or pharmacist.

If you have been given more ORITAXIM than you should

Since a health care provider will administer ORITAXIM, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of ORITAXIM

Since a health care provider will administer ORITAXIM, it is unlikely that the dose will be missed.

4. Possible side effects

ORITAXIM can have side effects.

Not all side effects reported for ORITAXIM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ORITAXIM, please consult your health care provider for advice.

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause

difficulty in swallowing or breathing

- Rash or itching
- 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 ORITAXIM. 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:

- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers (neutropenia).
- Bleeding or bruising more easily than normal (thrombocytopenia).
- Fever, rash, enlarged kidneys, low back pain, painful urination, abnormal urination frequency (kidney problems).
- Nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine, inflammation of liver (hepatitis, jaundice).
- Fits (convulsions).

- Severe diarrhoea, usually with blood and mucus, stomach pain, fever (pseudomembranous colitis).
- Pain at the site of injection, skin redness or inflammation, swelling (oedema) of the extremities (ankle and foot), palpable cord-like veins (thrombophlebitis).

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

Tell your doctor if you notice any of the following:

Frequent

- Tenderness and pain with redness and/or swelling at the site of injection

Less frequent

- Diarrhoea
- Decreased number of red blood cells
- Tendency to bleed/bruise easily
- Infection in gut (colitis)
- Lack of awareness, loss of consciousness
- Inability to control movements

Frequency unknown

- Dizziness
- Irregular heart rhythm
- Nausea and vomiting
- Stomach cramps or pain
- Dehydration
- Confusion and anxiety
- Fever
- Sores in the mouth and throat

- Trouble breathing
- Joint pain
- Fatigue
- Burning sensation with urination
- Sweating
- Bloody, watery diarrhoea
- Vaginal itching or soreness
- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)

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, 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 ORITAXIM.

5. How to store ORITAXIM

Store all medicines out of reach of children.

Do not remove the product form the outer carton until required for use.

Dry Powder: Store below 25°C, protected from light.

Do not use after the expiry date stated on the label or carton.

If the reconstituted solution cannot be used immediately, it may be kept for 24 hours in the refrigerator at 2-8 °C and for 24 hours at below 25 °C, when reconstitution/dilution is carried

out under validated aseptic conditions. Discard any unused portion. Note that the reconstituted solution should not be used if there are any signs of turbidity.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What ORITAXIM contains

The active substance is cefotaxime sodium equivalent to cefotaxime.

ORITAXIM 500: Each vial contains cefotaxime sodium equivalent to 0,5 g cefotaxime.

ORITAXIM 1 000: Each vial contains cefotaxime sodium equivalent to 1,0 g cefotaxime.

What ORITAXIM looks like and contents of the pack

Dry Powder: Off-white to pale-yellow powder.

Reconstituted solution: A pale-yellow solution.

ORITAXIM 500: 10 ml clear colourless glass vial, 20 mm grey butyl stoppers with a 20 mm aluminium flip off opaque green coloured seal.

ORITAXIM 1 000: 10 ml clear colourless glass vial, 20 mm grey butyl stoppers with a 20 mm aluminium flip off blue coloured seal.

Holder of Certificate of Registration

PHARMA-Q (PTY) LTD

50 Commando Road

Industria West, 2093

Johannesburg

South Africa

info@pharmaq.co.za

Tel: 011 247 1600

This leaflet was last revised in

8 August 2025

Registration numbers

ORITAXIM 500: 36/20.1.1/0482

ORITAXIM 1 000: 36/20.1.1/0483

Access to the corresponding Professional Information

https://www.pharmaq.co.za