



Read all of this leaflet carefully before you start taking this medicine

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor, health care provider><or><pharmacist>.>

Prescription only medicine

In this leaflet:

- a) What Gramocef O 200 is and what it is used for
- b) Before you take Gramocef O 200
- c) How to take Gramocef O 200
- d) Possible side effects
- e) How to store Gramocef O 200
- f) Further information

a. What Gramocef O 200 is and what it is used for

Gramocef O 200 contains a medicine called Cefixime. This belongs to a group of antibiotics called ‘cephalosporins’.

Cefixime is used to treat infections caused by bacteria.

These include infections of the:

- Ear
- Nose, sinuses (such as sinusitis)
- Throat (such as tonsillitis, pharyngitis)
- Chest and lungs (such as bronchitis, pneumonia)
- Urinary system (such as cystitis and kidney infections)

b. Before you take Gramocef O 200

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to Cefixime, any other cephalosporin antibiotics including penicillin or to any of the other ingredients of this medicine.

- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat and tongue.

Do not take this medicine if the above applies to you. If you are not sure, talk to your doctor or your pharmacist before taking Cefixime.

Take special care with Cefixime

Check with your doctor or your pharmacist before taking this medicine if:

- You have ever had colitis
- You have kidney problems
- The person taking this medicine is a child under the age of 10

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

Taking other medicines

Please tell your doctor or your pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Cefixime can affect the way some other medicines work. Also some medicines can affect the way Cefixime works.

In particular, tell your doctor if you are taking the following:

- Medicines to thin the blood such as warfarin

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if

- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding or planning to breast feed

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast feeding.

Tests

If you require any tests (such as blood or urine tests) while taking this medicine, please make sure your doctor knows that you are taking Cefixime.

c. How to take Gramocel O 200

Taking this medicine

Always use Cefixime exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

- Take this medicine by mouth
- Swallow capsules whole with a drink of water
- If you feel the effect of the medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

Carefully read the label from the pharmacist. Ask your pharmacist if you are not sure about the dose to take. The medicine should be taken for the prescribed number of days.

How much to take

The usual dose is:

Adults, Elderly and Children over 10 years or weighing more than 50kg

1 or 2 capsules, daily depending on the severity of infection

People with kidney problems

- Your doctor may prescribe a lower dose

Children under 10 years old

- Cefixime Paediatric should be used instead

If you take more Cefixime than you should

If you have too much of this medicine, talk to your doctor straight away.

If you forget to take Cefixime

If you forget to take a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose

If you stop taking Cefixime

Do not stop taking this medicine without talking to your doctor. You should not stop taking Cefixime just because you feel better. This is because the infection may come back or get worse again.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

d. Possible side effects

Like all medicines, Cefixime can cause side effects, although not everybody gets them.

Tell your doctor straight away or go to the nearest hospital casualty department if you notice any of the following serious side effects – you may need urgent medical treatment:

- You have an allergic reaction. The signs may include: a rash, joint pain, swallowing or breathing problems, swelling of your lips, face, throat or tongue

- Blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flu-like symptoms and fever. This may be something called ‘Stevens-Johnson syndrome.’
- Severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also a feeling of being generally unwell, fever, chills and aching muscles. This may be something called ‘Toxic epidermal necrolysis’
- You have a skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious allergy to the medicine called ‘erythema multiforme’
- You get infections more easily than usual. This could be because of a blood disorder. This normally gets better after stopping the medicine
- You bruise or bleed more easily than normal. This could be because of a blood disorder. This normally gets better after stopping the medicine
- If your child gets nose bleeds, bleeding gums, chills, tiredness, pale skin (often with a yellow tinge), shortness of breath. This may be due to haemolytic anaemia.
- Changes in the way the kidneys are working or blood in your child’s urine

Stop taking this medicine and contact your doctor without delay if you get:

- Severe watery diarrhoea that will not stop and you are feeling weak and have a fever. This may be something called ‘Pseudomembranous colitis’

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days

- Feeling sick (nausea) or being sick (vomiting)
- Stomach pains, indigestion or wind
- Headaches
- Feeling dizzy
- Feeling itchy in the genital or vaginal area

Tell your doctor if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet

Blood tests: Cefixime can cause blood clots or small changes to the way the liver and kidney work. This would be shown up in blood tests. This is not common and goes back to normal after stopping this medicine.

e. How to store Gramocéf O 200

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on label

Store below 30° C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

f. Further information

What Gramocel O 200 contains

The active substance is Cefixime

The other ingredients are: Dibasic Calcium Phosphate; Colloidal Silicon Dioxide; Talc; Sodium Lauryl Sulphate; Magnesium Stearate; HEG Cap 2, L. Green/D Green Micro /Micro Printed

What Gramocel O 200 looks like and contents of the pack

L.Green/ D. Green coloured '2' Size capsules with Micro/Micro printed containing white to light yellow granular powder

Alu/Alu Blister pack of 10's

Name and full physical address of Marketing Authorization Holder and Manufacturing site

Marketing Authorization Holder

MICRO LABS LIMITED

31, Race course road

Bangalore-560001

INDIA

Manufacturer

MICRO LABS LIMITED

No.121-124, 4th phase K.I.A.D.B

Bommasandra Industrial Area, Anekal Taluk

Bangalore-560099 INDIA

For any information about this medicinal product, please contact the <local representative of the> supplier:

Country: Rwanda

M/s.Wessex

Pharmaceuticals (Rwanda) Ltd

C/o.Phillips Pharmaceuticals (Rwanda) Ltd

Shop No: Gf68, Kigali Modern City Market Commercial Street

Kigali, Rwanda

This leaflet was last approved in

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