



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

a. What Gramocef-CV is and what it is used for

Gramocef CV contains two ingredients, Cefixime and Clavulanic acid. The first ingredient, Cefixime, is a cephalosporin antibiotic which treats infection by killing the bacteria responsible for the infection. Some bacteria are able to produce a chemical which makes Cefixime less effective. The second ingredient, Clavulanic acid, stops this from happening. Clavulanic acid stops the chemical produced by the bacteria from working, and this allows the Cefixime to kill the bacteria

Cefixime-Clavulanate is indicated for the treatment of:

- Uncomplicated Urinary Tract Infections
- Otitis Media
- Pharyngitis and Tonsillitis
- Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis
- Uncomplicated gonorrhoea (cervical/urethral)

b. Before you take Gramocef-CV

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to Cefixime-Clavulanate, 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-Clavulanate.

Taking with other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Cefixime and Clavulanic acid Tablets can affect the way some other medicines work. Also some medicines can affect the way Cefixime and Clavulanic acid Tablets work.

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

- Medicines to thin the blood such as warfarin

Pregnancy and breast-feeding

If you are pregnant, you think you might be pregnant or if you are breast-feeding, please tell your doctor or pharmacist. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Cefixime-Clavulanate can have side effects and the symptoms may make you unfit to drive. Don't drive or operate machinery unless you are feeling well.

c. How to take Gramocéf-CV

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Take this medicine by mouth
- 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.

If you take more Cefixime and Clavulanic acid Tablets than you should: If you have too much of this medicine, talk to your doctor straight away.

If you forget to take Cefixime and Clavulanic acid Tablets: 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 and Clavulanic acid Tablets: Do not stop taking this medicine without talking to your doctor. You should not stop taking this medicine 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 medicine, ask your doctor or pharmacist.

d. Possible side effects

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

Tell your doctor straightaway 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 may also 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), and 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.
- Fits (convulsions) – frequency not known
- A brain condition with symptoms including fits (convulsions), feeling confused, feeling less alert or aware of things than usual, unusual muscle movements or stiffness. This may be

something called ‘encephalopathy’.. This side effect is more likely if you have taken an overdose or you already have a problem with your kidneys

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 and Clavulanic acid Tablets can cause blood clots or small changes to the way the liver and kidneys work. This would be seen in blood tests. This is not common and goes back to normal after stopping this medicine.

e. How to store Gramocef-CV

Keep out of the reach and sight of children.

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

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 Gramocef-CV contains

The active substance are: Cefixime & Potassium Clavulanate

The other ingredients are: Microcrystalline Cellulose, Talc, Colloidal Silicon Dioxide, Magnesium Stearate, Croscarmellose Sodium, Hydroxy Propyl Methyl Cellulose, Diethyl Phthalate, Titanium Dioxide.

What Gramocéf-CV looks like and contents of the pack

Oblong shaped white coloured film coated tablets with ML embossing on both sides.

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

--