WHAT IS IN THIS LEAFLET

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1. WHAT GRAMOCEF DS IS AND WHAT IT IS USED FOR

Cefixime 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)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE GRAMOCEF DS

Do not take Cefixime DS if

- You are allergic (hypersensitive to Cefixime or any of the other ingredients of Cefixime.

You are allergic (hypersensitive to any other cephalosporin type of Antibiotic.
You have ever had a sever allergic reaction to penicillin or to any other beta-lactam type of antibiotic.

- You have severe kidney problem.
- Preterm and new-born infants (0-27 days)

Take special care with Cefixime

Yon should tell your doctor before taking this medicine if:

- You are allergic to penicillin antib1ot10 or to any other beta-lactam type of antibiotics.
  Not all people who are allergic to penicillin are also allergic to cephalosporin.
  However you should take special care if you have ever had an allergic reaction to penicillin. This is because you might also be allergic to this medicine.
- You develop sever allergic reaction or anaphylaxis (serious allergic reaction which causes difficulty in breathing or dizziness) after takinf1; Cefixime, in1orm your doctor immediately. The medicine should be withdrawn and appropriate treatment should be given.
- Yon have any kidney problems. If you are taking any sort of treatment (like dialysis) for kidney failure, you may need n lower dose of Cefixime, The use of Cefixime in the pediatric and adolescent age group is not recommended.
- You develop severe or prolonged diarrhoea during or after taking Cefixime, consult your doctor immediately.

Effect on laboratory tests
If yon are to undertake any blood or urine tests, inform your doctor that you are taking Cefixime, as Cefixime can alt.er the results of some of these tests.

Cefixime can alter the results of some urine tests for sugar (such as Benedict's or Fehling's tests). If you have diabetes and routinely test your urine, tell your doctor. This is because other tests may have to be used to monitor your diabetes while you are taking this medicine.
Cefixime may alter the results of a blood test for antibodies called the Coombs· test

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription,
If taken with Cefixime, the levels and therefore the effect of the following medicines may be increased in particular:

- Warfarin (blood thi1111er)
- Nifedipine, a calcium channel blocker, may increase bioavailability of Cefixime up to 70%

Taking Cefixime with food and drink
Food/meals have no effect on the medicine. Cefixime can be taken with or without food

Pregnancy and breast-feeding
If you are pregnant, likely to become pregnant or breast-feeding, you must tell your doctor before taking 1his medicine.
Ask your doctor or pharmacist for advice before taking any medicine

Driving and using machines
Cefixime does not usually affect your ability to drive or use machines, however. If you feel light-headed or dizzy, do not drive or operate machinery.

Important information about some of the ingredients of Cefixime
This medicine product contains sucrose. If yon have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE GRAMOCEF DS

Always fake Cefixime exactly your doctor has told you. Yon should check with your doctor or pharmacist if you me not sure. Your doctor will decide the rite dose of Cefixime and how long to take if for. Do not stop taking Cefixime early even of your symptom improve. It is important to take this medicine for a long as the doctor has told yon to.
Otherwise the infection might come back

- This medicine can be taken as single dose or in two divided dose.
- If your doctor prescribed one dose a day, it should be taken every 24 hours
- If your doctor has prescribed two dose a day, each do>e should be taken early 12 hours, You may find it is convenient to take one dose in the morning and the other in the evening. The medicine should always be taken at the same time each day.

The usual dose is:

Adult including children over 10years of age*:* The usual dose is 200-400 mg daily.
Elderly: For elderly patients, the doses are the same as adults provided that your kidney function is normal.
Children less than 10 years of age: The dose depends on your child's weight. Your doctor will prescribe the exact amount to give to your child.

Patients with kidney problems: In patient with kidney problems. The dose of Cefixime can be reduced. Your doctor will tell you exactly how much to take according to the result of blood of urine tests that measure how well your kidneys working and also according to the severity of your infection.
Children less *than 6 months of age:* Cefixime should not be given to children under 6 months of age.

How lo take Cefixime
The powder comes with a syringe (pipette), this should be used to help yon measure the exact amount of medicine yon need.
Follow these steps:

- Remove the child-proof cap. Push the plastic sc1'ew cap down while turning it counter clockwise
- Add 68 ml of water in two portions to the dry mixture in rho bottle
- Shake well after ead1 addition
- Insert the syringe into the bottle
- While holding the bottom ring, pull the top ring up to the mark that corresponds to the number of millilitres or mg you need to take
- Holding the bottom ring remove the entire syringe from the bottle
- Empty the syringe and take the dose
- Close the bottle tightly and store the bottle below 25°C
- Rinse the syringe with some water, ready for re-use
- Make sure to shake the bottle well before each use.

If you take more Cefixime than yon should
Contact your doctor or nearest hospital immediately. Take the container with yon.

If you forget to take Cefixime
Take the next dose as soon as you remember unless it is almost time for next dose.
Do not lake a double dose to make up fo1 a forgotten dose.

If you stop taking Cefixime
Do not stop taking Cefixime because you feel better. It is important to take the dose for as long as your doctor told you to, otherwise the problem might come back if you have any further questions on the use of this product,

4. POSSIBLE SIDE EFFECTS

Very common:	affect more than 1 people in 10
Common:	affects 1 to 10 people in 100
Uncommon:	affects 1 to 10 people in 1,000
Rare:	affects 1 to 10 people in 10,000
Very rare:	affects less than 1 people in 10.000
Not known:	frequency cannot be estimated from the available data

If any of rile following happen, stop taking Cefixime and tell your doctor lmm1.1t1inh•ly or go to your nearest hospital emergency department:

- Severe diarrhoea with blood in the stools during ofaf1er 1aktng Cefixime. Diarrhoea may occur over two months; after treatment with Cefixime.
- Dark urine, pale stools. Jaundice (yellowing of the skin and or eyes). nausea, fever

- Allergic reactions including rashes hove been reported with Cefixime. In very rare cases, difficulty in breathing, fainting and swelling of 1he face and throat can occur which may need emergency treatment Allergic rashes may range in severity from mild itchy skin emptions to a rarer, more serious condition called Stevens Johnson syndrome (which may cause ulceration of the mouth, lip~ and skin) or toxic epidermal necrolysis (which causes severe illness and sloughing of the skin).
- In the unlikely even that your infection has been caused by a hug; which Cefixime cannot treat, your symptoms may get worse. If this happens, you should consult your doctor.

Common side effects (affecting fewer than 1 in 10 people)

- Diarrhoea

Uncommon side effects (affecting fewer than 1 in 100 people)

- Headache
- Nausea
- Vomiting
- Stomach (abdominal) pain
- Changes in blood tests that show how your liver is working
- Skin rash

Rare side effects (affecting fewer than 1 in 1,000 people)

- Infections caused by germs that Cefixime does not act on. For example thrush
- Loss of appetite (anorexia)
- Flatulence (wind)
- Changes in blood test that show how your kidney is working
- fever
- allergy reaction
- dizziness
- itchy skin
- inflammation of the linin;: of the mouth and or internal surfaces

Very Rare side effects (affecting fewer than 1 in 1,000 people)

- fall in the number of different cells in the blood (symptoms can include tiredness, new infections and easy bruising or bleeding)
- restlessness and increased activity
- liver problems including Jaundice (yellowing of the skin or whites of eyes)
- inflammation of the kidney
- pseudomembranous colitis

5. HOW TO STORE GRAMOCEF DS

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on carton and bottle after EXP.

Store unopened bottle should not be stored above 25° C.

After reconstitution the suspension can be stored below 25°C for 14 days without significant loss of potency. Do not freeze. Keep bottles tightly dosed and shake well before use. Discard any unused portion after 14 days. Dilution of the suspension is not recommended.

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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What* GRAMOCEF DS*, contains,

Cefixime USP as Trihydrate equivalent to anhydrous Cefixime 50 mg (Gramocef-O-50 DS)
Cefixime USP as Trihydrate equivalent to anhydrous Cefixime 100 mg (Gramocef-O-100 DS)

What Gramocef DS looks like and contents of the pack,

Carton containing 100 ml amber coloured bottle having 50.0 g powder.

Manufacturer

Micro Labs Limited
No. 121-124, 4th Phase, K.I.A.D.B.,
Bommasandra Industrial Area,
Anekal Taluk, Bangalore-560 099, INDIA.

Marketing Authorization Holder

MICRO LABS LIMITED
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