Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking KEFLOR CD?

KEFLOR CD contains the active ingredient cefaclor. KEFLOR CD is used to treat infections caused by bacteria in different parts of the body. For more information, see Section <u>1</u>. Why am I taking KEFLOR CD? in the full CMI.

2. What should I know before I take KEFLOR CD?

Do not take if you have ever had an allergic reaction to KEFLOR CD, other cephalosporins, or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before I take KEFLOR CD? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with KEFLOR CD and affect how it works. A list of these medicines is in Section <u>3. What if I am</u> taking other medicines? in the full CMI.

4. How do I take KEFLOR CD?

- Your doctor will tell you how much KEFLOR CD you need to take. This will depend on the type of infection you have.
- Swallow the tablets whole with a full glass of water. Do not cut, crush or chew the tablet.

More instructions can be found in Section <u>4. How do I take KEFLOR CD?</u> in the full CMI.

5. What should I know while taking KEFLOR CD?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are taking KEFLOR CD. Tell your doctor if the symptoms of your infection do not improve within a few days, or if they become worse. If you become pregnant while taking this medicine, tell your doctor immediately.
Things you should not do	 Do not take KEFLOR CD to treat any other complaints unless your doctor tells you to. Do not give your medicine to anyone else, even if they have the same condition as you. Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	Be careful driving or operating machinery until you know how KEFLOR CD affects you.
Looking after your medicine	 Keep the pack in a cool, dry place (below 25°C) in its original packaging. Do not store KEFLOR CD in the bathroom, near a sink, on a window sill or in the car. Keep your tablets where children cannot reach it.

For more information, see Section 5. What should I know while taking KEFLOR CD? in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist if you notice any of the following: diarrhoea, itchy rash, oral thrush - white, furry, sore tongue or mouth, vaginal thrush - sore and itchy vagina and/or abnormal discharge. Tell your doctor as soon as possible if you notice any of the following: nausea, vomiting, drowsiness, headache, hyperactivity, nervousness, insomnia, confusion, dizziness, hallucinations, severe muscle stiffness, swelling of the joints with or without fever, Tell your doctor immediately if you notice any of the following, particularly if they occur several weeks after stopping treatment with KEFLOR CD: severe abdominal cramps or stomach cramps; watery and/or severe diarrhoea which may also be bloody; fever, in combination with one or both of the above. Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of the following: rash, itching or hives on the skin with swelling of the face, lips, tongue or other parts of the body; seizures; confusion, memory loss, personality changes, trouble thinking clearly or focusing; involuntary muscle movements such as jerks, tremors or eye movements. This is not a complete list of all possible side effects. For more information, including what to do if you have any side effects, see Section <u>6</u>. Are there any side effects? in the full CMI.

KEFLOR[®] CD

Active ingredient(s): cefaclor (as monohydrate)

Consumer Medicine Information (CMI)

This leaflet provides important information about taking KEFLOR CD. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking KEFLOR CD.

Where to find information in this leaflet:

- 1. Why am I taking KEFLOR CD?
- 2. What should I know before I take KEFLOR CD?
- 3. What if I am taking other medicines?
- 4. How do I take KEFLOR CD?
- 5. What should I know while taking KEFLOR CD?
- 6. Are there any side effects?
- 7. Product details

1. Why am I taking KEFLOR CD?

KEFLOR CD contains the active ingredient cefaclor

monohydrate. KEFLOR CD belongs to a group of medicines called cephalosporins. This medicine works by killing the bacteria that are causing your infection.

KEFLOR CD is used to treat infections caused by bacteria in different parts of the body. This includes infections of the:

- ears, nose, throat and tonsils (upper respiratory tract)
- chest and lungs (lower respiratory tract)
- bladder and kidneys (lower urinary tract)
- skin

Your doctor may have prescribed it for another reason.

There is no evidence that it is addictive.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

2. What should I know before I take KEFLOR CD?

Warnings

Do not take KEFLOR CD if:

- you are allergic to any medicine containing cefaclor monohydrate, other cephalosporins, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
 - o shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin

Always check the ingredients to make sure you can take this medicine.

• you have had a serious allergic reaction to penicillin.

Do not give this medicine to a child under the age of 12 years.

Safety and effectiveness in children younger than 12 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- are allergic to any other medicines or any foods, preservatives or dyes.
- have or have had any of the following medical conditions:
 - o kidney disease
 - o severe bowel conditions
 - o liver disease

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

If you have not told your doctor about any of the above, tell them before you start taking KEFLOR CD.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and KEFLOR CD may interfere with each other. These include:

- antacids, a medicine used to neutralise stomach acid to relieve heartburn, indigestion or an upset stomach
- probenecid, a medicine used to treat gout and to promote the excretion of uric acid

These medicines may be affected by KEFLOR CD or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect KEFLOR CD.

4. How do I take KEFLOR CD?

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

- Your doctor will tell you how much KEFLOR CD you need to take. This will depend on the type of infection you have.
- Follow the instructions provided when KEFLOR CD was prescribed, including the number of days it should be taken.

How to take it

- Swallow the tablets whole with a full glass of water.
- Do not cut, crush or chew the tablet.

When to take KEFLOR CD

• Take your medicine at about the same time each day with food.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

• If you need to take an antacid, take it at least 1 hour before or 1 hour after you take KEFLOR CD.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

It is important to complete the full course prescribed by your doctor, even if you begin to feel better after a few days. If you do not complete the full course, the bacteria causing your infection may continue to grow and multiply. This means your infection may not clear completely and your symptoms may return.

If you forget to take KEFLOR CD

If you miss your dose at the usual time and it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much KEFLOR CD

If you think that you or anyone else may have taken too much KEFLOR CD, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include vomiting, upset stomach or diarrhoea.

5. What should I know while taking KEFLOR CD?

Things you should do

- Tell your doctor if the symptoms of your infection do not improve within a few days, or if they become worse.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking KEFLOR CD, especially if you are about to be started on any new medicine.
- If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

• Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

 If you are diabetic, check with your doctor or pharmacist before using urine sugar tests.

KEFLOR CD may cause false test results with some urine sugar tests.

Call your doctor straight away if you:

• become pregnant while taking KEFLOR CD.

Things you should not do

- Do not take KEFLOR CD to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

Driving or using machines

Be careful driving or operating machinery until you know how KEFLOR CD affects you.

This medicine may cause dizziness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they may not keep well.
- Keep your tablets in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking KEFLOR CD.

This medicine helps most people with certain bacterial infections, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 diarrhoea itchy rash oral thrush - white, furry, sore tongue or mouth vaginal thrush - sore and itchy vagina and/or abnormal discharge 	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
	The list includes the more common side effects of KEFLOR CD. They are usually mild and short- lived.

Serious side effects

Serious side effects	What to do
 nausea vomiting drowsiness headache hyperactivity, nervousness, insomnia, confusion, dizziness, hallucinations severe muscle stiffness swelling of the joints with or without fever pain in the joints with or without fever itching or swelling of the skin yellowing of the skin or eyes frequent infections such as fever, severe chills, sore throat or mouth ulcers bleeding or bruising more easily than normal difficulty in swallowing or breathing 	Speak to your doctor as soon as possible if you have any of these serious side effects and they worry you. The list includes serious side effects which may require medical attention.
notice any of the following, particularly if they occur several weeks after stopping treatment with KEFLOR CD:	
 severe abdominal cramps or stomach cramps watery and/or severe diarrhoea which may also be bloody fever, in combination with one or both of the above 	

Do not take any diarrhoea medicine without first checking with your doctor.

You may have a serious condition affecting your bowel, requiring urgent medical attention.

More serious side effects

More serious side effects	What to do
 sudden signs of allergy such as	Call your
rash, itching or hives on the skin	doctor straight
with swelling of the face, lips,	away, or go
tongue or other parts of the	straight to the

More serious side effects	What to do
 body, shortness of breath, wheezing or trouble breathing seizures signs of encephalopathy such as confusion, memory loss, personality changes, trouble thinking clearly or focusing signs of myoclonus such as involuntary muscle movements such as jerks, tremors or eye movements, which may occur alone or in combination with encephalopathy 	Emergency Department at your nearest hospital if you notice any of these more serious side effects. The list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What KEFLOR CD contains

Active ingredient (main ingredient)	cefaclor monohydrate equivalent to 375 mg of cefaclor
Other ingredients (inactive ingredients)	 hypromellose mannitol Colour Mixture Dark Blue YS-1-4273 (ARTG PI No. 1444) hyprolose methacrylic acid copolymer stearic acid propylene glycol magnesium stearate purified talc
Potential allergens	N/A

What KEFLOR CD looks like

KEFLOR CD is a coated compressed tablet. Blue paracapsule shaped, dual radii, 7.62mm, approx length 16mm (AUST R 58655).

Available in blister packs of 10 tablets.

Who distributes KEFLOR CD

Alphapharm Pty Ltd trading as Viatris Level 1, 30 The Bond 30-34 Hickson Road Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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 KEFLOR^* is a Viatris company trade mark

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