

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using KEFLOR?

KEFLOR contains the active ingredient cefaclor. KEFLOR is used to treat infections caused by bacteria in different parts of the body. For more information, see Section [1. Why am I using KEFLOR?](#) in the full CMI.

2. What should I know before I use KEFLOR?

Do not use if you have ever had an allergic reaction to KEFLOR 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 use KEFLOR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with KEFLOR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use KEFLOR?

- Your doctor will tell you how much KEFLOR you need to take.
- This will depend on the type of infection you have.

More instructions can be found in Section [4. How do I use KEFLOR?](#) in the full CMI.

5. What should I know while using KEFLOR?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using KEFLOR.• 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	<ul style="list-style-type: none">• Do not take KEFLOR 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	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how KEFLOR affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep KEFLOR suspension in your refrigerator at 2°C to 8°C where young children cannot reach it. Do not freeze.• Keep the bottle tightly closed.• The suspension should be shaken well before use and discarded after 14 days.

For more information, see Section [5. What should I know while using KEFLOR?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist if you notice any of the following and they worry you: 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, 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 or difficulty in swallowing or breathing. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

KEFLOR®

Active ingredient(s): *cefaclor (as monohydrate)*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I using KEFLOR?](#)
- [2. What should I know before I use KEFLOR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use KEFLOR?](#)
- [5. What should I know while using KEFLOR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using KEFLOR?

KEFLOR contains the active ingredient **cefaclor monohydrate**. KEFLOR belongs to a group of antibiotics called cephalosporins. These antibiotics works by killing the bacteria that are causing your infection.

KEFLOR 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

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

Your doctor may have prescribed it for another reason.

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

This medicine is not addictive.

2. What should I know before I use KEFLOR?

Warnings

Do not use KEFLOR 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:
 - 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 use this medicine.

Do not take KEFLOR if you have had a serious allergic reaction to penicillin.

Do not give this medicine to a child under the age of one month.

Safety and effectiveness in children younger than one month have not been established.

Do not take this medicine after the expiry date printed on the carton and bottle label 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:
 - kidney disease
 - severe bowel conditions
 - liver disease

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

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

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 may interfere with each other. These include:

- probenecid (e.g. Pro-Cid), a medicine used to treat gout and to promote the excretion of uric acid

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking KEFLOR.

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.

4. How do I use KEFLOR?

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 carton or bottle, ask your doctor or pharmacist for help.

How much to take

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

How to take it

- **Shake the bottle well and accurately measure the dose with a medicine measure.**
- Shaking the bottle and using a medicine measure will make sure that you get the correct dose. You can buy a medicine measure from your pharmacist.
- It does not matter if you take this medicine with or without food.

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, the bacteria causing your infection may continue to grow and multiply so that your infection may not clear completely or your symptoms may return.

If you forget to take KEFLOR

If 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.

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

If you think that you have used too much KEFLOR, you may need urgent medical attention.

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.

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

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

5. What should I know while using KEFLOR?

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 this medicine.**

- **If you become pregnant while taking this medicine, tell your doctor immediately.**
- **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 may cause false test results with some urine sugar tests.

Things you should not do

- **Do not take KEFLOR 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 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.

Children should be careful when riding bicycles or climbing trees.

Looking after your medicine

Keep KEFLOR suspension in your refrigerator at 2°C to 8°C where young children cannot reach it. Do not freeze.

Keep the bottle tightly closed.

The suspension should be shaken well before use and discarded after 14 days.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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.

This medicine helps most people with infection, 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.

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

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

Ask your doctor or pharmacist to answer any questions you may have.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • diarrhoea • itchy rash • oral thrush - white, furry, sore tongue or mouth • vaginal thrush - sore and itchy vagina and/or abnormal discharge <p>The above list includes the more common side effects of KEFLOR. They are usually mild and short-lived.</p>	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 <p>The above list includes serious side effects which may require medical attention</p> <p>Tell your doctor immediately if you notice any of the following, particularly if they occur several weeks after stopping treatment with KEFLOR:</p> <ul style="list-style-type: none"> • 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 	<p>Speak to your doctor as soon as possible if you have any of these serious side effects and they worry you.</p>

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
<ul style="list-style-type: none"> • sudden signs of allergy such as rash, itching or hives on the skin with swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing <p>The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these more serious side effects.</p>

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 www.tga.gov.au/reporting-problems. 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 contains

Active ingredient (main ingredient)	<p>KEFLOR 125 mg/5 mL contains 25 mg/mL mg of cefaclor as the active ingredient.</p> <p>KEFLOR 250 mg/5 mL contains 50 mg/mL mg of cefaclor as the active ingredient.</p>
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • sucrose • erythrosine • methylcellulose • sodium lauryl sulfate • strawberry flavour 52312 AP0551 (ARTG PI No: 274) • dimeticone 350 • xanthan gum • pregelatinised starch
Potential allergens	KEFLOR contains sugars.

Do not take this medicine if you are allergic to any of these ingredients.

What KEFLOR looks like

Your pharmacist will make up the medicine in the bottle before dispensing it to you. The resulting suspension is pink and has a strawberry taste.

It is available in two different strengths:

- 125 mg/5 mL (AUST R 58651)

- 250 mg/5 mL (AUST R 58653)

Sponsor

Alphapharm Pty Ltd trading as **Viatrix Pty Ltd**

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