

# KEFLOR®

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## Consumer Medicine Information (CMI) summary

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

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### 1. Why am I taking 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 taking KEFLOR?](#) in the full CMI.

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

Do not take if you have ever had an allergic reaction to KEFLOR, 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?](#) 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 take KEFLOR?

- Your doctor will tell you how much KEFLOR you need to take. This will depend on the type of infection you have.
- Shake the bottle well and accurately measure the dose with a medicine measure. More instructions can be found in Section [4. How do I take KEFLOR?](#) in the full CMI.

### 5. What should I know while taking KEFLOR?

#### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking 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

	<p>medicine, tell your doctor immediately.</p>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not take KEFLOR to treat any other complaints unless your doctor tells you to.</li> <li>● Do not give your medicine to anyone else, even if they have the same condition as you.</li> <li>● Do not stop taking your medicine or lower the dosage without checking with your doctor.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● Be careful driving or operating machinery until you know how KEFLOR affects you.</li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>● Keep KEFLOR suspension in your refrigerator at 2°C to 8°C where young children cannot reach it. Do not freeze.</li> <li>● Keep the bottle tightly closed.</li> <li>● The suspension should be shaken well before</li> </ul>

	take and discarded after 14 days.
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For more information, see Section [5. What should I know while taking KEFLOR?](#) 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, vaginal thrush. **Tell your doctor as soon as possible if you notice any of the following:** nausea, vomiting, drowsiness, headache, hyperactivity, 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:** 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 [6. Are there any side effects?](#) in the full CMI.



# KEFLOR®

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

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## Consumer Medicine Information (CMI)

This leaflet provides important information about taking 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 taking KEFLOR.**

**Where to find information in this leaflet:**

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

## 1. Why am I taking 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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

## **2. What should I know before I take KEFLOR?**

### **Warnings**

#### **Do not take 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 take this medicine.

- 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

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**

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.**

### **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, 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 take 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**

KEFLOR should be used regularly at the same time each day.

**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.**

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 or anyone else may have taken too much KEFLOR, 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 feeling sick, vomiting, upset stomach or diarrhoea.

## **5. What should I know while taking 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 KEFLOR, especially if you are about to be started on any new medicines .

- 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.

### **Call your doctor straight away if you:**

- become pregnant while taking KEFLOR.

### **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 take and discarded after 14 days.

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

### **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 use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use 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.**

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.

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

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>● nausea</li><li>● vomiting</li><li>● drowsiness</li><li>● headache</li><li>● hyperactivity, nervousness, insomnia, confusion, dizziness, hallucinations</li><li>● severe muscle stiffness</li><li>● swelling of the joints with or without fever</li><li>● pain in the joints with or without fever</li><li>● itching or swelling of the skin</li><li>● yellowing of the skin or eyes</li><li>● frequent infections such as fever, severe chills, sore throat or mouth ulcers</li><li>● bleeding or bruising more easily than normal</li><li>● difficulty in swallowing or breathing</li></ul>	<p><b>Speak to your doctor as soon as possible if you have any of these serious side effects and they worry you.</b></p> <p>The list includes serious side effects which may require medical attention.</p>

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Tell your doctor immediately if you notice any of the following, particularly if they occur several weeks after stopping treatment with KEFLOR:</b></p> <ul style="list-style-type: none"> <li>● severe abdominal cramps or stomach cramps</li> <li>● watery and/or severe diarrhoea which may also be bloody</li> <li>● fever, in combination with one or both of the above</li> </ul>	

**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

<b>More serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>● 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</li><li>● seizures</li><li>● signs of encephalopathy such as confusion, memory loss, personality changes, trouble thinking clearly or focusing</li><li>● signs of myoclonus such as involuntary muscle movements such as jerks, tremors or eye movements, which may occur alone or in combination with encephalopathy</li></ul>	<p><b>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.</b></p> <p>This list includes very serious side effects. You may need urgent medical attention or hospitalisation.</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](http://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

<b>Active ingredient (main ingredient)</b>	KEFLOR 125 mg/5 mL contains 25 mg/mL of cefaclor.  KEFLOR 250 mg/5 mL contains 50 mg/mL of cefaclor.
<b>Other ingredients</b>	<ul style="list-style-type: none"><li>• sucrose</li><li>• erythrosine</li></ul>

<b>(inactive ingredients)</b>	<ul style="list-style-type: none"> <li>● methylcellulose</li> <li>● sodium lauryl sulfate</li> <li>● strawberry flavour 52312 AP0551 (ARTG PI No: 274)</li> <li>● dimeticone 350</li> <li>● xanthan gum</li> <li>● pregelatinised starch</li> </ul>
<b>Potential allergens</b>	Sugars

## What KEFLOR looks like

KEFLOR 125 mg/5 mL: A pink free-flowing dry powder. After reconstitution, it is a red coloured suspension with a characteristic strawberry odour (AUST R 58651).

Available in bottle of 100 mL.

KEFLOR 250 mg/5 mL: A pink free-flowing dry powder. After reconstitution, it is a red coloured suspension with a characteristic strawberry odour (AUST R 58653).

Available in bottle of 75 mL.

## Who distributes KEFLOR

Alphapharm Pty Ltd trading as Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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KEFLOR® is a Viatris company trade mark

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