

Keflor(R)

contains the active ingredient cefaclor (monohydrate)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Keflor.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Keflor against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What Keflor is used for

Keflor is used to treat infections in different parts of the body caused by bacteria. Keflor can be used to treat infections of the:

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

Your doctor may have prescribed Keflor for another reason. Ask your doctor if you have any questions about why Keflor has been prescribed for you.

Keflor is an antibiotic that belongs to a group of medicines called cephalosporins. These medicines

work by killing the bacteria that are causing your infection.

Keflor will not work against infections caused by viruses, such as colds or flu.

Keflor is available only with a doctor's prescription.

There is no evidence that Keflor is addictive.

Before you take Keflor

When you must not take it

Do not take Keflor if you are allergic to medicines containing:

- * cefaclor monohydrate
- * any other cephalosporin
- * any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take Keflor if you have had a severe allergic reaction to penicillin.

Do not give this medicine to a child under the age of 1 month.

Safety and effectiveness in children younger than 1 month have not been established.

Do not take Keflor 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.

Before you start to take it

Tell your doctor if you have had any type of allergic reaction to penicillin antibiotics.

You may have an increased chance of being allergic to Keflor if you are allergic to penicillins.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

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

Tell your doctor if you have or have had any of the following medical conditions:

- * kidney disease
- * liver disease
- * bowel disease
- * bleeding problems.

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

Taking other medicines

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

Some medicines may be affected by Keflor or may affect how well Keflor works. These include:

- * anticoagulants, medicines used to prevent blood clots
 - * salicylates or non steroidal anti-inflammatory drugs (NSAIDs), medicines used to treat pain or inflammation
 - * probenecid, a medicine used to treat gout
 - * antacids, medicines used to treat heartburn and indigestion.
- Antacids may interfere with the absorption of Keflor. To make sure there is no problem with absorption, do not take antacids within one hour of taking Keflor.

Talk to your doctor about the need for additional contraception while taking Keflor.

Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with Keflor.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take Keflor

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.

Adults: The usual adult dose is 250 mg every 8 to 12 hours.

Children: The dose for children will depend on the child's weight. Your doctor and pharmacist will tell you how much Keflor your child should take.

How to take Keflor

Always shake the bottle well before measuring the correct amount to take.

When to take it

Take Keflor at about the same time each day.

This will allow Keflor to have its best effect and also help you remember when to take it.

Keflor can be taken with or without food.

How long to take it for

Keep taking Keflor until you finish the bottle, or for as long as your doctor recommends.

Keep taking Keflor for the full time of treatment, even if you begin to feel better after a few days.

If you do not complete the full course prescribed by your doctor, your infection may not clear completely or your symptoms may return.

If you forget to take

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 the missed dose as soon as you remember, and then go back to taking Keflor 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 (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or

go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much Keflor. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you have taken too much Keflor, you may feel sick in the stomach, vomit or experience diarrhoea.

While you are taking Keflor

Things you must do

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

If you develop itching with swelling or skin rash or difficulty breathing while you are taking Keflor, tell your doctor immediately or go to Accident and Emergency at the nearest hospital.

If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after stopping Keflor.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any medicines for diarrhoea without first checking with your doctor.

If you get a sore, white mouth or tongue while taking or soon after stopping Keflor, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes the use of Keflor allows fungi to grow and the above symptoms to occur. Keflor does not work against fungi.

If you become pregnant while you are taking Keflor, tell your doctor.

If you are about to start taking a new medicine, tell your doctor or pharmacist that you are taking Keflor.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Keflor.

If you have to have any blood tests, tell your doctor that you are taking Keflor.

Keflor may affect the results of some tests.

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.

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.

Things you must not do

Do not stop taking Keflor or lower the dose because you are feeling better, unless advised by your doctor.

If you do not complete the full course prescribed by your doctor, your infection may not clear completely or your symptoms may return.

Do not take Keflor to treat any other complaints unless your doctor tells you to.

Do not give Keflor to anyone else, even if they have the same condition as you

Things to be careful of

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

Keflor generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Keflor may cause dizziness or drowsiness in some people. If any of these occur,

do not drive, operate machinery or do anything else that could be dangerous.

Side effects

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

Keflor treats infections in most people, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

Tell your doctor if you notice any of the following and they worry you:

- * diarrhoea
- * nausea (feeling sick), vomiting
- * headache
- * stomach (abdominal) pain or discomfort
- * nose bleed
- * unusual tiredness or weakness
- * oral thrush (white, furry sore tongue and mouth)
- * vaginal thrush (sore and itchy vagina, vaginal discharge).

The above list includes the more common side effects of Keflor. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- * watery and severe diarrhoea, which may also be bloody
- * fever
- * hallucinations (seeing, feeling, or hearing things that are not there)
- * nervousness, confusion
- * hyperactivity, insomnia

- * unusual muscle stiffness
- * swelling or pain in the joints, with or without fever
- * yellowing of the skin or eyes
- * frequent infections such as fever, severe chills, sore throat or mouth ulcers.

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- * signs of allergy such as rash, itching, hives on the skin, with swelling of the face, lips, tongue or other parts of the body, which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

The above list includes very serious side effects which are very rare. You may need urgent medical attention or hospitalisation.

After you have finished taking Keflor

Tell your doctor immediately if you notice any of the following, even if they occur several weeks after stopping treatment with Keflor:

- * watery and severe diarrhoea, which may also be bloody
- * severe stomach cramps
- * fever, in combination with one or both of the above.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Some of these side effects can only be found when your doctor does tests from time to time to check your progress. These include:

- * swelling of the liver
- * inflammation of the kidney.

After using Keflor

Storage

Keep your medicine where children cannot reach it.

Keep the suspension in the bottle until it is time to take it.

Keep Keflor suspension in the refrigerator but not in the freezer, and keep the bottle tightly closed. Do not use any mixture that is left in the bottle after 14 days.

Do not keep Keflor or any other medicine in the bathroom or near a sink.

Do not leave Keflor in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

Keflor suspensions comes in two strengths:

- * Keflor 125 mg/5 mL
- * Keflor 250 mg/5 mL.

Both strengths of Keflor Suspension are pink and have a strawberry taste.

Each bottle of Keflor 125 mg/5 mL contains 100 mL of mixture.

Each bottle of Keflor 250 mg/5 mL contains 75 mL of mixture.

Ingredients

The active ingredient in Keflor suspensions is cefaclor (as cefaclor monohydrate).

- * each 5 mL of Keflor 125 mg/5 mL contains 125 mg of cefaclor
- * each 5 mL of Keflor 250 mg/5 mL contains 250 mg of cefaclor.

The suspensions also contain the following inactive ingredients:

- * sucrose
- * erythrosine CI45430 (E 127)
- * methylcellulose
- * sodium lauryl sulfate
- * artificial strawberry flavour
- * dimethicone 350
- * xanthan gum F
- * modified tapioca starch.

Keflor suspensions are gluten free.

Supplier

Keflor is supplied by:

Alphapharm Pty Limited
(ABN 93 002 359 739)
Chase Building 2
Wentworth Park Road
Glebe NSW 2037

Phone: (02) 9298 3999

Medical Information

Phone: 1800 028 365

Australian registration numbers:

Keflor 125 mg/5 mL - Aust R 58651

Keflor 250 mg/5 mL - Aust R 58653

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