

## KEFLEX®

cephalexin monohydrate

### Consumer Medicine Information

#### what is in this leaflet

This leaflet answers some common questions about Keflex. It does not contain all the available information. It does not take the place of talking with your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Keflex 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 the medicine.**

You may need to read it again.

#### What Keflex is used for

Keflex contains cephalexin monohydrate as the active ingredient.

It is used to treat infections caused by bacteria in different parts of the body, including infections of the:

- respiratory tract (throat, tonsils, chest and lungs)
- nose (sinusitis)
- ears (otitis media)
- skin and soft tissue
- kidneys and bladder (genitourinary tract).

This medicine belongs to a group of medicines called cephalosporins. These antibiotics work by killing the bacteria that are causing your infection.

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

Your doctor may have prescribed it for another reason.

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

There is no evidence that it is addictive.

#### Before you take it

##### *When you must not take it*

**Do not take Keflex if you have an allergic reaction to:**

- any medicine containing cephalexin monohydrate
- other cephalosporins
- any of the ingredients listed at the end of this leaflet.

**Do not take this medicine if you have had a serious allergic reaction to penicillin.**

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.

**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.

**Do not take Keflex suspension if it has been in your refrigerator for longer than two weeks.**

**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 are allergic to any other medicines or any foods, preservatives or dyes.**

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

- liver disease
- kidney disease
- bowel disease.

**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.

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

#### *Taking other medicines*

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

Some medicines and Keflex may interfere with each other.

These include:

- probenecid (e.g. Pro-Cid), a medicine commonly used to treat gout
- metformin, a medicine used in the treatment of diabetes.

These medicines may be affected by Keflex 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 or pharmacist has more information on medicines to be careful with or avoid while taking Keflex.

#### How to take it

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

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 and how often you should take Keflex.**

This will depend on the type of infection. The dose varies from patient to patient.

#### *How to take it*

##### **Keflex capsules:**

Swallow the capsules whole with a full glass of water.

##### **Keflex suspension:**

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.

#### *When to take it*

It does not matter if you take this medicine with or without food.

#### *How long to take it*

**Continue taking Keflex 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 not clear completely or your symptoms may return.

#### *If you forget to take it*

**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 (overdose)*

**Immediately telephone your doctor or Poisons Information Centre (13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Keflex. 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 in the stomach, diarrhoea, blood in the urine, unusually increased reflexes, convulsions or hallucinations.

#### While you are taking it

##### *Things you must 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 are treating you that you are taking Keflex, especially if you are about to be started on any new medicines.**

**Tell your doctor if you become pregnant while taking this medicine.**

**If you are about to have any blood tests, tell your doctor that you are taking Keflex.**

It may interfere with the results of some tests.

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

Keflex may affect the results of some of these 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 take Keflex 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 change the dosage without first checking with your doctor.**

If you stop taking it, your condition may worsen.

### Things to be careful of

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

It may cause dizziness or drowsiness in some people.

Children should be careful when riding bicycles or climbing trees.

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### Side effects

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

This medicine helps most people with infection but it may have unwanted side effects in a few people.

All medicines 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.

#### 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:

- sore or white mouth or tongue (oral thrush)
- sore and itchy vagina and/or discharge (another form of thrush)
- diarrhoea
- nausea
- vomiting
- dizziness
- unusual tiredness/weakness
- abdominal pain
- headache.

The above list includes the more common side effects of your medicine.

#### Tell your doctor as soon as possible if you notice any of the following and they worry you:

- severe body rash
- swelling of face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- fever
- swelling of the joints
- yellowing of the skin or eyes
- joint pain
- confusion and hallucinations
- bleeding or bruising more easily than normal.

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

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

- severe stomach cramps or pain
- severe, watery or bloody diarrhoea
- fever, in combination with one 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.

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

- 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.

This is a very serious side effect. You may need urgent medical attention or hospitalisation. This side effect is very rare.

#### Tell your doctor or pharmacist if you notice anything else 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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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### After taking it

#### Storage

##### Keflex capsules:

- **Keep the capsules in the blister pack until it is time to take them.**  
If you take the capsules out of the blister pack, they may not keep as well.
- **Keep it in a cool dry place where the temperature stays below 30°C (for the 250 mg capsules) and below 25°C (for the 500 mg capsules).**
- **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.
- **Do not store it or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**  
Heat and dampness can destroy some medicines.

##### Keflex suspension:

- **Keep the suspension in the refrigerator between 2 and 8°Celsius 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.**

#### Disposal

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.

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### Product Description

#### What it looks like

##### Keflex capsules:

- Keflex 250 mg capsules are opaque dark green and white, marked with "GP1" on the cap and body. They are available in packs of 20.
- Keflex 500 mg capsules are opaque dark green and light green, marked with "GP2" on the cap and body. They are available in packs of 20.

##### Keflex suspension:

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

It is available in two different strengths:

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

### Ingredients

#### Keflex capsules:

Keflex capsules contain cephalexin monohydrate equivalent to 250 mg or 500 mg of cephalexin as the active ingredient.

They also contain the inactive ingredients:

- dimethicone 350
- magnesium stearate
- avicel RC 591.

The capsule shell contains gelatin, patent blue V, quinoline yellow, titanium dioxide and colorcon S-1-8144 HV black ink.

Keflex capsules do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

#### Keflex suspension:

Keflex suspensions contain 125 mg/5 mL or 250 mg/5 mL of cephalexin monohydrate as the active ingredient.

They also contain:

- sodium lauryl sulphate
- methylcellulose
- dimethicone 350
- xanthan gum
- starch - pregelatinised maize
- allura red AC CI 16035
- sucrose
- tutti frutti 51880 TP0551.

Keflex suspensions do not contain lactose, gluten or tartrazine.

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### Sponsor

#### Aspen Pharmacare Australia Pty Limited

34-36 Chandos St  
St Leonards NSW 2065

#### Australian Registration Numbers

##### for Keflex products are:

250 mg capsule: AUST R 73522  
500 mg capsule: AUST R 73523

125 mg/5 mL suspension:  
AUST R 92970

250 mg/5 mL suspension:  
AUST R 92971

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