## **APO-Cephalexin**

## **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 APO-Cephalexin?

APO-Cephalexin contains the active ingredient cefalexin monohydrate. APO-Cephalexin is used to treat infections in different parts of the body caused by bacteria.

For more information, see Section 1. Why am I using APO-Cephalexin? in the full CMI.

## 2. What should I know before I use APO-Cephalexin?

Do not use if you have ever had an allergic reaction to APO-Cephalexin 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 APO-Cephalexin? in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with APO-Cephalexin 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 APO-Cephalexin?

- Continue taking APO-Cephalexin 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.

More instructions can be found in Section 4. How do I use APO-Cephalexin? in the full CMI.

## 5. What should I know while using APO-Cephalexin?

Things you should do	<ul> <li>Tell your doctor, dentist or pharmacist you visit that you are using APO-Cephalexin.</li> <li>Tell your doctor immediately if you become pregnant or start breastfeeding.</li> <li>If you are going to have surgery, tell your surgeon or anesthetist.</li> <li>If you are diabetic, check with your doctor or pharmacist before using urine sugar tests.</li> </ul>
Things you should not do	<ul> <li>Do not stop using this medicine because you are feeling better, unless advised by a doctor.</li> <li>Do not give your medicine to anyone else, even if they have the same condition or symptoms as you.</li> <li>Do not take a double dose to make up the dose that you missed</li> </ul>
Driving or using machines	Be careful as this medicine may cause dizziness or tiredness     Children may also be affected so they should be watched carefully if riding bikes or climbing
Drinking alcohol	There are no known interactions
Looking after your medicine	<ul> <li>Store below 25°C protected from light and moisture</li> <li>Keep your medicine in its original packaging until it is time to take it</li> </ul>

For more information, see Section 5. What should I know while using APO-Cephalexin? in the full CMI.

### 6. Are there any side effects?

Common side effects may include dizziness, tiredness, weakness or headache, mild diarrhoea or stomach upsets/pain, oral or vaginal thrush, itching in the genital or anal areas. Serious side effects include fever, itching or any type of skin rash, blistering or peeling, aching or swollen muscles or joints, severe vomiting, diarrhoea and/or stomach pain, skin or eyes yellowing, pale stools, dark urine, bleeding or bruising more easily than normal, feeling agitated, confused or seeing or hearing things, symptoms of an allergic reaction (eg. shortness of breath, difficulty breathing, swelling of face, lips, tongue, throat)

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.

# **APO-Cephalexin**

Active ingredient: cefalexin monohydrate

## **Consumer Medicine Information (CMI)**

This leaflet provides important information about using APO-Cephalexin. 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 APO-Cephalexin.

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

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

## 1. Why am I using APO-Cephalexin?

**APO-Cephalexin contains the active ingredient cefalexin monohydrate.** APO-Cephalexin belongs to a group of antibiotics called cephalosporins that are closely related to penicillins. It works by killing the bacteria causing your infection or by stopping its growth.

APO-Cephalexin is used to infections in different parts of the body caused by bacteria such as:

- respiratory tract (chest, lungs, tonsils or throat)
- sinuses
- ears (middle ear infection)
- skin
- genitourinary tract (kidney, bladder or prostate).

Cefalexin will not work against infections caused by viruses such as colds or the flu.

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

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

There is no evidence that this medicine is addictive.

## 2. What should I know before I use APO-Cephalexin?

#### Warnings

#### Do not use APO-Cephalexin if:

 you are allergic to cefalexin (or other cephalosporins), or any of the ingredients listed at the end of this leaflet.

- Always check the ingredients to make sure you can use this medicine.
- if it is after the expiry date printed on the pack
- if the packaging is torn or shows sign of tampering

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

#### Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have allergies to cephalosporins, penicillins or other antibiotics
- have allergies to any other medicines, foods, preservatives or dyes
- have or have had an intolerance or allergic reason to lactose
- have or have had kidney or liver disease
- have or have had severe bowel conditions / 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.

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 this medicine.

## 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 may interfere with APO-Cephalexin and affect how it works:

- Probenecid (used to treat gout or prolong the action of certain antibiotics)
- Metformin (used to treat diabetes)

These medicines may be affected by cefalexin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

## 4. How do I use APO-Cephalexin?

#### How much to take / use

Your doctor or pharmacist will tell you how many capsules you will need to take. This depends on your infection, your condition and whether or not you are taking any other medicines.

- Adults: The usual adult dose is one 250mg capsule taken every six hours. Your doctor may recommend a different dose depending on your condition.
- Children: Your child's doctor will tell you how much cefalexin your child should take. This will depend on your child's age, weight and the type of infection.

Continue taking APO-Cephalexin 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.

#### When to take / use APO-Cephalexin

 It does not matter if you take APO-Cephalexin with or without food

#### How to take APO-Cephalexin

• Swallow the capsules with a glass of water

#### If you forget to use APO-Cephalexin

APO-Cephalexin 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 you missed.

If you are not sure what to do, ask your doctor or pharmacist. Ask your pharmacist for some hints if you have trouble remembering to take your medicine.

#### If you use too much APO-Cephalexin

If you think that you have used too much APO-Cephalexin, you may need urgent medical attention.

#### You should immediately:

 phone the Poisons Information Centre (by calling 13 11 26), 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.

## 5. What should I know while using APO-Cephalexin?

#### Things you should do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed 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.

If you are diabetic, check with your doctor or pharmacist before using urine sugar tests. Cefalexin may affect the results of some of these tests.

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

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

If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after cefalexin has been stopped. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any medicine for diarrhoea without first checking with your doctor or pharmacist.

If you get a sore white mouth or tongue while taking or soon after stopping cephalexin, tell your doctor. Also tell your doctor if you get vaginal itching or discharge. This may mean you have fungal infection called thrush.

#### Things you should not do

- unless advised by your doctor, o not stop using this
  medicine because you are feeling better. If you do not
  complete the full course prescribed by your doctor, all
  the bacteria causing your infection may not be killed.
  These bacteria may continue to grow and multiply so
  that your infection may not clear completely, or it may
  return.
- do not give your medicine to anyone else, even if they have the same condition as you
- do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to

#### **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how APO-Cephalexin affects you.

APO-Cephalexin may cause dizziness or tiredness in some people.

Children may also be affected so they should be carefully watched if riding bikes or climbing.

#### **Drinking alcohol**

Tell your doctor if you drink alcohol.

#### Looking after your medicine

Store 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 young children cannot reach it.

#### When to discard your medicine (as relevant)

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

#### 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?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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> <li>oral thrush (white, furry, sore tongue and mouth)</li> <li>vaginal thrush (sore and itchy vagina and/or discharge)</li> <li>itching in the genital / anal areas</li> <li>mild diarrhoea</li> <li>mild stomach upsets, such as indigestion, feeling sick and/or being sick (nausea or vomiting)</li> <li>abdominal pain</li> <li>dizziness, tiredness, weakness or headache</li> </ul>	Speak to your doctor if you have any of these less serious side effects and they worry you.

#### Serious side effects

berious side effects			
Serious side effects	What to do		
<ul> <li>fever</li> <li>itching or any type of skin rash or blistering, peeling or flaking skin</li> <li>aching or swollen muscles, joints or joint pain.</li> <li>severe vomiting and/or stomach pain</li> <li>yellowing of the skin or eyes, and/or pale stools, dark urine (jaundice)</li> <li>watery and severe diarrhoea, which may also be bloody</li> <li>bleeding or bruising more easily than normal, frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> <li>feeling agitated, confused or seeing or hearing things that are not there.</li> <li>severe abdominal cramps or stomach cramps</li> <li>seizure potential</li> <li>severe blisters and bleeding in mucosal sites (such as lips, eyes, mouth, nose, genitals) that may cause the skin to peel, sometimes occurring with fever and flu-like symptoms</li> <li>symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin</li> </ul>	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.		

# 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 <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. 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 APO-Cephalexin contains

Active ingredient (main ingredient)	cefalexin monohydrate  • lactose monohydrate
Other ingredients (inactive ingredients)	<ul> <li>gelatin</li> <li>iron oxide yellow</li> <li>brilliant blue FCF</li> <li>sunset yellow FCF</li> <li>titanium dioxide</li> <li>magnesium stearate</li> <li>TekPrint SW-9008 black ink</li> <li>purified water</li> </ul>
Potential allergens	lactose; may contain trace amounts of sulfites

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

## What APO-Cephalexin looks like

#### 250 mg capsules (AUST R 73870):

Dark green and white, self-locked hard gelatin capsules of size 2, imprinted with RX656 in black ink, containing white to off-white granular powder/pellets.

#### 500 mg capsules (AUST R 133852)

Dark green and light green, self-locked hard gelatin capsules of size 0, imprinted with RX657 in black ink, containing white to off-white granular powder/pellets.

Blister packs of 20 capsules.

## Who distributes [medicine name]

Arrotex Pharmaceuticals Pty Ltd 15 – 17 Chapel Street Cremorne VIC 3121 www.arrotex.com.au

This leaflet was prepared in December 2023.