

Proprietary name:	Cefpodoxime 100 mg Alkem & Cefpodoxime 200 mg Alkem
Dosage form:	Tablets
Active Ingredient:	Cefpodoxime (as proxetil)
Strength per dosage unit:	100 mg or 200 mg per tablet

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Cefpodoxime 100 mg Alkem Film-coated Tablets

Cefpodoxime 200 mg Alkem Film-coated Tablets

Cefpodoxime (as proxetil)

Read all of this leaflet carefully before you start taking Cefpodoxime Alkem.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

Cefpodoxime Alkem has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **Cefpodoxime Alkem** is and what it is used for
2. What you need to know before you take **Cefpodoxime Alkem**
3. How to take **Cefpodoxime Alkem**
4. Possible side effects
5. How to store **Cefpodoxime Alkem**
6. Contents of the pack and other information

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1. WHAT CEFPODOXIME ALKEM IS AND WHAT IT IS USED FOR

What Cefpodoxime Alkem is:

Cefpodoxime Alkem contains an active substance called cefpodoxime. **Cefpodoxime Alkem** is an antibiotic used to kill bacteria, which cause infection in your body. It belongs to a group of antibiotics called cephalosporins.

What Cefpodoxime Alkem is used for:

Your doctor has prescribed **Cefpodoxime Alkem** because you have one (or more) of the following types of infection:

- Tonsillitis (infection on the tonsil)
- Pharyngitis (infection of the throat)
- Sinusitis (infection of the sinus)
- acute chest infection in patients with chronic bronchitis
- pneumonia (infections in the lungs)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CEFPODOXIME ALKEM

Do not take Cefpodoxime Alkem:

- If you are allergic to cefpodoxime or other cephalosporins or any of the other ingredients of **Cefpodoxime Alkem** (listed in section 6).
- If you have had a severe allergic reaction to particular antibiotics (penicillins, monobactams and carbapenems) as you may also be allergic to Cefpodoxime.
- If you are pregnant or breastfeeding your child.
- If your child is under the age of 1 year.

Tell your doctor before you start on **Cefpodoxime Alkem** if you think that this applies to you: *You must not be given Cefpodoxime Alkem.*

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Warnings and Precautions:

Take special care with **Cefpodoxime Alkem**:

- If you have ever been told that your kidneys do not work very well. Also, if you are having any sort of treatment (like dialysis) for kidney failure. You may take **Cefpodoxime Alkem** but you may need a lower dose.
- If you have ever had inflammation of your bowel, called colitis or any other severe disease affecting your gut.
- if you have to have tests such as cross-matching blood and the coomb's test because **Cefpodoxime Alkem** can alter the results of some blood tests. It is important to tell the doctor that you are taking **Cefpodoxime Alkem**.
- If you have diabetes and routinely test your urine, tell your doctor. This is because other tests may have to be used to monitor your diabetes while you are having **Cefpodoxime Alkem**. **Cefpodoxime Alkem** can also alter the results of urine tests for sugar (such as Benedict's or Fehling's tests).

Talk to your doctor or pharmacist if any of the above applies to you.

Other medicines and Cefpodoxime Alkem:

Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary and traditional medicines).

This medicine can be affected by other medicines that are removed by the kidneys. This is especially if these other medicines also affect how well kidneys work. There are many medicines that can do this, so should check with your doctor or pharmacist before taking this medicine.

In particular, tell your doctor or pharmacist if you are taking:

- antacids (used to treat indigestion)
- anti-ulcer medicines (used to treat ulcer) such as ranitidine or cimetidine

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- diuretics (used to increase urine flow)
- aminoglycoside antibiotics used to treat infections
- probenecid (used in the treatment of gout)
- anti-coagulants e.g. warfarin

Antacids and anti-ulcer treatments (such as ranitidine and cimetidine) should be taken 2 - 3 hours after taking **Cefpodoxime Alkem**. Your doctor knows about these and will alter the treatment if considered necessary.

If you require any tests (blood, urine or diagnostic), whilst taking this medicine, please ensure that your doctor knows that you are taking **Cefpodoxime Alkem**.

Pregnancy and breast-feeding:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Cefpodoxime Alkem.

Your doctor will consider the benefit of treating you with **Cefpodoxime Alkem** against the risk to your baby.

Driving and using machines:

If you are experiencing dizziness after having taken this medicine, you should not drive vehicles or operate machinery.

Cefpodoxime Alkem contains lactose.

If you have been told by your doctor that you have intolerance to some sugars contact your doctor before taking this medicine.

Cefpodoxime Alkem contain sunset yellow FCF (E110). It may cause allergic reaction.

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3. HOW TO TAKE CEFPODOXIME ALKEM

Do not share medicines prescribed for you with any other person.

Always take **Cefpodoxime Alkem** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist, if you are not sure.

How much Cefpodoxime Alkem to take:

The dosage depends on the condition being treated.

Adults and children:

Tonsillitis (infection of the tonsils), pharyngitis (throat infection) and acute bronchitis (chest infection):

The usual dose is one **Cefpodoxime 100 mg Alkem** tablet twice daily with meals (200 mg per day). Treatment must continue for at least 10 days.

Acute sinusitis (Infection of the sinuses), acute exacerbations of chronic bronchitis (worsening chest infection), pneumonia (infection of the lungs):

The usual dose is one **Cefpodoxime 200 mg Alkem** tablet twice daily with meals (400 mg per day).

Elderly patients:

It is not necessary to adjust the dose as long as there are no kidney problems.

Patients with liver problems (adults and children):

It is not necessary to adjust the dose.

Patients with kidney problems (adults and children):

It is not necessary to adjust the dose in patients with mild kidney problems. For patients with moderate kidney problems, the daily dosage regimen should be reduced by half and be taken as a single daily dose. The dose should be reduced by half and taken every second day for severe cases of kidney problems, and after each dialysis session for haemodialysis patients.

Your doctor will tell you how much to take each time.

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Your doctor will tell you how long your treatment with **Cefpodoxime Alkem** will last. If you have the impression that the effect of **Cefpodoxime Alkem** is too strong or too weak, tell your doctor or pharmacist.

How to take Cefpodoxime Alkem:

It is important that you take your medicine at the right time of day. You should always take the tablets with food because food helps the tablets to absorb.

If you take more Cefpodoxime Alkem than you should:

If you accidentally take too much of **Cefpodoxime Alkem**, contact your doctor or pharmacist who will recommend what action you should take.

If you forget to take Cefpodoxime Alkem:

If you forget to take a dose of your medicine at the correct time, you should take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose. Just take the next dose at the correct time. Carry on as before.

If you stop taking Cefpodoxime Alkem:

Keep taking your medicine until your doctor has told you to stop. Do not stop **Cefpodoxime Alkem** just because you feel better. If you stop taking the medicine, your condition may reoccur or get worse.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Cefpodoxime Alkem can cause side effects.

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Not all side effects reported for **Cefpodoxime Alkem** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **Cefpodoxime Alkem**, please consult your healthcare provider for advice.

If any of the following happens, stop taking **Cefpodoxime Alkem** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- **Severe allergic reaction.** Signs include raised and itchy rash, swelling, sometimes of the face or mouth causing difficulty in breathing, bronchospasms, purpura and oedema of the face and extremities.
- Worsening in the kidney function.
- Liver damage

These are all serious side effects. If you have them, you may have had a serious reaction to **Cefpodoxime Alkem**. You may need urgent medical attention or hospitalisation. Tell your doctor if you notice any of the following:

Frequent side effects:

- Stomach problems: Bloating nausea, vomiting, stomach pain, flatulence (wind) and diarrhoea.

If you have severe diarrhoea or if you see blood in your diarrhoea you should stop taking this medicine and talk to your doctor immediately.

- Eating problems: loss of appetite.

Less frequent side effects:

- Hypersensitivity reactions (These are skin rashes that are less severe allergic reactions than mentioned above, lumpy rash (hives), itching)
- Headaches
- Pins and needles

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- Dizziness
- Ringing in the ears
- Weakness and a feeling of generally being unwell.
- Changes in blood tests that check how your liver is working
- Anaemia: a type of anaemia that can be severe and is caused by red blood cells breaking up.
- Drops in the numbers of blood cells (symptoms can include tiredness, new infections and easy bruising or bleeding)
- Increase in some types of white blood cells
- Increase in the numbers of small cells that are needed for clotting of the blood.
- Having a course of **Cefpodoxime Alkem** can temporarily increase the chance that you can get infections caused by other sorts of germs. For example, thrush may occur.

Frequency unknown side effects:

- **Skin rash**, which may blister, and looks like small targets (central dark spot surrounded by a paler area, with a dark ring around the edge).
- **A widespread rash with blisters and peeling skin.** (These may be signs of Stevens-Johnson syndrome or toxic epidermal necrolysis).

Most of the side effects are mild to moderate and will generally disappear after a few days to a few weeks of treatment.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist or nurse>. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s

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publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **Cefpodoxime Alkem**.

5. HOW TO STORE CEFPODOXIME ALKEM

Store at or below 25 °C (Room temperature).

Store in the original package. Keep the blister in the outer carton.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton, the blister and the bottle.

Do not throw away any medicines in drains or sewage systems.

Return all unused medicine to the pharmacist.

6. CONTENTS OF PACK AND OTHER INFORMATION

What Cefpodoxime Alkem contains:

The active ingredient is cefpodoxime (as proxetil).

Cefpodoxime 100 mg Alkem: Each film-coated tablet contains 130.44 mg cefpodoxime proxetil equivalent to 100 mg cefpodoxime.

Cefpodoxime 200 mg Alkem: Each film-coated tablet contains 260.88 mg cefpodoxime proxetil equivalent to 100 mg cefpodoxime.

Other ingredients: Carboxymethyl cellulose calcium, colloidal silicon dioxide, crospovidone (Type B), hypromellose, low-substituted hydroxy propyl cellulose, lactose monohydrate, macrogol, magnesium stearate, sodium lauryl sulfate) and colourants (FD&C Yellow #5 (E102), FD&C Yellow #6 (E110), red iron oxide (E172) and titanium dioxide (E171)

What Cefpodoxime Alkem looks like and contents of the pack:

Cefpodoxime 100 mg Alkem: Orange colored, oval shaped, film-coated tablets debossed with "A55" on one side and plain on other side.

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Cefpodoxime 200 mg Alkem: Orange colored, oval shaped, film-coated tablets debossed with "A57" on one side and plain on other side.

Holder of Certificate of Registration

Ascend Laboratories (Pty) Ltd.

R21 Corporate Park,

121 Sovereign Drive, Block A, Office 202

Irene Ext. 30, Centurion, 0157

This leaflet was last revised in

May 2020

Application Numbers:

Cefpodoxime 100 mg Alkem: 540471.469

Cefpodoxime 200 mg Alkem: 540472.470

Access to the corresponding Professional Information

The professional information will be included in each unit pack of the product.