

Cefalexin Tablets 250 mg or 500 mg

(cefaalexin)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or dentist (if the medicine has been prescribed by your dentist).
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, talk to your doctor, pharmacist or dentist (if the medicine has been prescribed by your dentist). This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1 What Cefalexin Tablets is and what it is used for

The name of your medicine is Cefalexin Tablets. This medicine belongs to a family of medicines called antibiotics. Antibiotics are used to kill the bacteria or "germs" which cause infections.

Your doctor, or dentist, will have prescribed this medicine for treating an infection. Cefalexin Tablets are used for treating a variety of infections including chest (respiratory tract), urinary tract, skin and soft tissues, ear, and other infections.

2 What you need to know before you take Cefalexin Tablets

Do not take Cefalexin tablets if you:

- are allergic to cefalexin or other cephalosporins (similar antibiotics) and medicines.
- are allergic to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

- Talk to your doctor or pharmacist before taking Cefalexin tablets if you have had an allergic reaction to cefalexin, cephalosporins, penicillins, or other drugs in the past
- develop diarrhoea
- are pregnant or breast-feeding. Your doctor will decide whether it is safe for you to take this medicine while you are pregnant or breast-feeding.
- have problems with your kidneys.
- test your urine for glucose using a method which is not based on glucose oxidation reactions as this medicine might give a false positive result.
- are about to have a blood test, as Cefalexin tablets can interfere with a Coombs test.
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking cefalexin or other antibacterials

If any of the above apply to you or you are unsure, please talk to your doctor before taking the tablets.

Take special care with cefalexin:

Acute generalised exanthematous pustulosis (AGEP) has been reported with the use of cefalexin. AGEP appears at the initiation of treatment as a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The most common location: mainly localized on the skin folds, trunk, and upper extremities. The highest risk for occurrence of this serious skin reaction is within the first week of treatment. If you develop a serious rash or another of these skin symptoms, stop taking cefalexin and contact your doctor or seek medical attention immediately.

Other medicines and Cefalexin tablets

Tell your doctor or pharmacist if you are taking, have recently

taken or might take any other medicines, even those not prescribed, particularly:

- Uricosuric drugs (medicines used to treat gout and other conditions which require lowering of blood uric acid levels, e.g. probenecid).
- Diuretics (medicines which reduce water retention by increasing the volume of urine, e.g. furosemide, ethacrynic acid)
- Anticoagulants (medicines that prevent the clotting of blood, e.g. warfarin)
- Any other antibiotics (eg. aminoglycosides, polymyxin, colistin)
- If you are taking metformin (a medicine used to treat diabetes)
- Drugs used to treat leukaemia.

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 this medicine.

Driving and using machines

There are no effects on ability to drive or to operate machinery.

Cefalexin Tablets contains lactose

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

3 How to take Cefalexin Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Each dose should be swallowed with a drink of water.

Try to space the doses as evenly as possible throughout the day. For example, if you have been told to take Cefalexin Tablets three times a day in 8 hour intervals, then:

- Take your first dose when you wake up, e.g. 7.00 am
- Take your next dose mid-afternoon, e.g. 3.00 pm
- Take your last dose just before you go to bed, e.g. 11.00 pm.

If you have been told to take your medicine four times a day in approximately 6 hour intervals, then:

- Take your first dose when you wake up, e.g. 6.00 am
- Take your second dose around noon, e.g. 12.00 pm
- Take your third dose early evening, e.g. 6.00 pm
- Take your last dose when you go to bed, e.g. 11.00 pm.

Dosage Instructions

Your doctor will tell you how much to take and how often.

Do not take more than the dose your doctor has recommended.

Continued on the next page >>

Artwork Proof Box

Ref: VO41 : To update SPC, PIL with PRAC recommendations + RFI

Proof no. 007.1	Date prepared: 18/07/2018	Font size: 8pt
--------------------	------------------------------	-------------------

Colours: ■ Black <input type="checkbox"/>	<input type="checkbox"/>	Fonts: Helvetica
<input type="checkbox"/> Black 20% <input type="checkbox"/>	<input type="checkbox"/>	

Dimensions: 175 x 315 mm

Adults

The usual dose for adults is 1-4g daily in divided doses. For most infections the dose will be 500 mg (2 x 250 mg tablets or 1 x 500 mg tablet) every 8 hours.

This may vary depending on the type of infection you have. For example a dose of 250 mg (1 x 250 mg tablet) taken every 6 hours or 500 mg (2 x 250 mg tablets or 1 x 500 mg tablet) every 12 hours is used to treat skin, soft tissue, throat or urinary tract infections, or those caused by less susceptible organisms.

Older people

The dosage for the elderly is the same as for adults, but may be reduced if you have poor kidney function.

Use in children and adolescents

For most infections, the usual dose is; 125 mg (half a 250 mg tablet) every 8 hours for children under 5 years, or 250 mg (1 x 250 mg tablet) every 8 hours for children 5 years and over.

For skin and soft tissue infections, urinary tract infections and sore/dry throat caused by bacterial infections, the total daily dose may be divided and administered every 12 hours. In severe infections the dosage may be doubled, for certain infections such as ear infections doses even higher than double the normal above may be required. Infections caused by certain bacteria may require treatment for at least 10 days.

Keep taking your medicine until the course is finished. Do not stop taking your medicine just because you feel better. If you stop too soon the infection may start up again. If your symptoms persist, tell your doctor.

If you take more Cefalexin Tablets than you should

Always take your medicine as recommended by your doctor. If you take too much medicine, tell your doctor immediately or go to your local hospital emergency department.

If you forget to take Cefalexin Tablets

If you miss a dose, take another as soon as you remember and then carry on as before. Do not take a double dose to make up for a forgotten dose.

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

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor immediately if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

Serious side effects

The following side effects are serious. You should stop taking this medicine and contact your doctor immediately if you experience them:

- Serious peeling or blistering of the skin
- Severe diarrhoea.
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). See also section 2.

Other side effects

The following side effects have been reported

- Feeling of sickness or being sick
- Indigestion
- Diarrhoea (which may be bloody) or stomach pains
- Reversible liver disorder or jaundice (yellowing of the skin and eyes)
- Itching
- Red wheals on the skin (urticaria) (alone)
- Itching around the genitals or anus
- Thrush or discharge from the vagina
- rash with wide spread joint pain stiffness, swollen lymph glands, fever and, possibly, cloudy urine
- Dizziness
- Tiredness
- Headache
- Agitation, confusion and hallucinations
- Pain or swelling in the joints
- Kidney disorders or blood disorders, including an increase or decrease in the number of white blood cells, and a decrease in the number of platelets.

Symptoms of blood disorders include tiredness, sore throat, bruising easily and susceptibility to infection.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Cefalexin Tablets

Keep all medicines out of the sight and reach of children. Blister packs - Store in the original packaging, in order to protect the tablets from the light and moisture. Plastic containers - Keep the container tightly closed, in order to protect the tablets from light and moisture.

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Cefalexin Tablets contain:

The active ingredient of Cefalexin Tablets is either 250 mg or 500 mg of cefalexin. The film-coated tablets also contain magnesium stearate, povidone (E1201), sodium starch glycolate, macrogol 6000, lactose, saccharin sodium (E954), talc (E553b) and peppermint oil. The tablet coating contains titanium dioxide (E171) and hypromellose (E464).

Cefalexin Tablets 250 mg come in plastic containers of 20, 21, 28, 50, 100 and 500 and blister packs of 20, 21 and 28 tablets.

Cefalexin Tablets 500mg come in plastic containers of 12, 15, 20, 21, 24, 28, 50, 100, 250 and 500 tablets, and blister packs of 14, 15, 20, 21, 28, 30 and 56 tablets.

Cefalexin Tablets 250 mg are round, film-coated and white to yellowish in colour. The tablets are scored on one side and have "CX" above the score and "250" below. The unscored side is without markings.

Cefalexin Tablets 500 mg are oblong, film-coated and white to yellowish in colour. The tablets are scored on each side.

Product licence holder and manufacturer:

Sandoz GmbH, A 6250 Kundl, Tirol, Austria.

This leaflet was last revised in July 2018.

SZ00000LT000

Artwork Proof Box

Ref: V041 : To update SPC, PIL with PRAC recommendations + RFI

Proof no. 007.1	Date prepared: 18/07/2018	Font size: 8pt
Colours: <input checked="" type="checkbox"/> Black <input type="checkbox"/> Black 20%	<input type="checkbox"/>	Fonts: Helvetica

Dimensions: 175 x 315 mm