

Patient Information Leaflet

SCHEDULING STATUS: **S4**

CEFUGEN 250 Film-coated tablets

CEFUGEN 500 Film-coated tablets

(Cefuroxime axetil)

Sugar free

CEFUGEN 250 contains 155.28 mg sodium per tablet

CEFUGEN 500 contains 310.56 mg sodium per tablet

Read all of this leaflet carefully before you start taking CEFUGEN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CEFUGEN has been prescribed for you, and you should not share the medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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1. What CEFUGEN is and what it is used for

CEFUGEN tablets contain an active ingredient called cefuroxime. Cefuroxime is an antibiotic used in adults and children. It works by killing bacteria that cause infections. It belongs to a group of medicines called cephalosporins.

Cefuroxime is used to treat:

- throat infections
- sinus infections
- middle ear infections
- lung or chest infections
- urinary tract infections
- soft tissue infections

CEFUGEN can also be used to treat Lyme disease (an infection spread by parasites called ticks).

2. What you need to know before you take CEFUGEN**Do not take CEFUGEN:**

- If you or your child are allergic (hypersensitive) to cefuroxime or any of the other ingredients of CEFUGEN. See section 6.
- If you or your child have ever had a severe allergic (hypersensitive) reaction to other cephalosporin antibiotics.
- If you or your child have ever had a severe allergic (hypersensitive) reaction to any other type of beta-lactam antibiotic (penicillins, monobactams and carbapenems).

Warnings and precautions

Take special care with CEFUGEN:

- if you or your child have a history of gastro-intestinal (stomach-intestinal) conditions, especially ulcerative colitis (ulceration of the colon), pseudomembranous ('false membrane') colitis or enteritis (inflammation of the intestine)
- if you have renal impairment – a smaller dose may be needed
- you have porphyria – safety has not yet been evaluated.

Please inform your doctor before taking or giving CEFUGEN, even if these statements were applicable to you at any time in the past.

If you or your child have any symptoms, such as allergic reactions, fungal infections in the mouth (thrush) or vagina (vaginitis) caused by an overgrowth of yeast (Candida), stomach cramps, abdominal tenderness, severe and watery diarrhoea (pseudomembranous colitis) while you are taking or giving CEFUGEN.

Stop taking or giving CEFUGEN and contact your doctor or pharmacist immediately if these symptoms occur.

If you need a blood test

CEFUGEN can affect the results of a test for blood sugar levels, or a blood screen called the Coombs test. If you or your child need a blood test, tell the person taking the sample that you are taking CEFUGEN.

Children

Do not give CEFUGEN to children less than 3 months of age as no clinical trial data is available on the use of cefuroxime axetil in children under the age of 3 months.

Other medicines and CEFUGEN

Always tell your health care provider if you or your child are taking any other medicine. This includes all complementary or traditional medicines.

- Medicines used to reduce the amount of acid in your stomach (e.g. antacids used to treat heartburn)- it can affect how CEFUGEN works.
- Probenecid (used for gout) This may increase the levels of CEFUGEN in the blood.
- Medicines to help stop blood clots (such as warfarin)- - this may raise INR levels therefore extra blood tests and adjusting your dose may be needed.
- Contraceptive pill-CEFUGEN may reduce its effectiveness. It is important that an alternative or additional method of contraception such as condoms is used while being treated with CEFUGEN and taking the pill. Ask your doctor or pharmacist for advice.
- Furosemide - this may cause kidney damage.
- Aminoglycoside antibiotics (such as amikacin, gentamicin, kanamycin, neomycin, tobramycin) - this may also cause kidney damage.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine. Using CEFUGEN may interfere with the effectiveness of oral contraceptives, hence you need to use alternative or additional methods of contraception

while taking this medicine. The safety of CEFUGEN in pregnancy and breastfeeding has not been established. CEFUGEN is excreted into breast milk in small quantities. The use of CEFUGEN by breastfeeding mothers may lead to the baby becoming sensitive, developing diarrhoea and fungal infections, hence you should consult with your doctor before commencing or consider the possibility of stopping treatment.

Driving and using machines

CEFUGEN can cause dizziness and have other side effects and the symptoms may make you less alert. Do not drive or operate machinery unless you are feeling well.

3. How to take CEFUGEN

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

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

Your doctor will tell you how long your treatment with CEFUGEN will last. Do not stop treatment early because you are feeling better. If you have the impression that the effect of CEFUGEN is too strong or too weak, tell your doctor or pharmacist.

Adults

The recommended dose of CEFUGEN is 250 mg to 500 mg twice daily depending on the severity and type of infection. The usual course of treatment is 7 days, ranging from 5 to 10 days.

Pharyngitis and tonsillitis: 250 mg twice daily

Otitis media: 500 mg twice daily

Sinusitis and bronchitis: 250 mg twice daily

Acute and chronic bronchitis: 250 mg twice daily

Acute uncomplicated cystitis: 250 mg twice daily

Lyme disease: 500 mg twice daily for 14 days. (range 10-21 days).

Children 12 years and older

Lyme disease: 500 mg twice daily for 14 days. (range 10-21 days)

How to take CEFUGEN

- CEFUGEN should be taken half an hour after food. This will help to make the treatment more effective. Swallow CEFUGEN whole with water.
- Do not chew, crush or split the tablets - this may make the treatment less effective and will have a bitter taste, therefore the tablets unsuitable if you or your child cannot swallow tablets.
- There are other forms of cefuroxime axetil available, and depending on the dosage, your doctor may prescribe these to you or your child if you cannot swallow tablets.

If you take more CEFUGEN than you should

If you have too much CEFUGEN, you may have neurological disorders, in particular you may be more likely to have fits (seizures). In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take CEFUGEN

- If you forget to take a dose, take it as soon as you remember.
- Do not take a double dose to make up for forgotten individual doses.

If you stop taking CEFUGEN

Keep taking CEFUGEN until the treatment is finished, even if you feel better. You need every dose to help fight the infection. If some bacteria survive, they can cause the infection to come back and make the medicine less effective due to resistance.

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

4. Possible side effects

CEFUGEN can have side effects.

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

If any of the following happens, stop taking / using CEFUGEN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- **Hypersensitivity reactions** (An excessive response by the body to a foreign substance) such as skin rashes, hives, itching and bronchospasm (tight chest).
- Swelling of the mouth, lips, or throat.
- Severe skin reactions such as blisters, sores, or ulceration.
- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease).
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).
- **Pseudomembranous colitis** (stomach cramps or pain, severe watery diarrhoea which may also be bloody and fever).

These are all very serious side effects. If you have them, you may have had a serious reaction to CEFUGEN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Fungal infections in the mouth or vagina (Candidiasis).
- Nausea (Uncomfortable sensation in the stomach along with an urge to vomit),
- Stomach cramps
- Diarrhoea (loose or watery stools)

Less frequent side effects:

- Skin rashes
- Allergic reactions (including severe)
- Severe diarrhoea
- Fever
- Yellowing of the whites of the eyes or skin
- Inflammation of the liver (hepatitis)
- Hearing loss in children with meningitis
- Headache
- Convulsions
- Clostridium difficile overgrowth
- Jarisch-Herxheimer reaction
- Angioneurotic oedema

Side effects that may show up in your blood tests:

- an increase in a type of white blood cell (eosinophilia)
- a decrease in the number of blood platelets, which are cells that help blood to clot (thrombocytopenia)
- a decrease in the number of white blood cells (leukopenia)
- red blood cells destroyed too quickly (haemolytic anaemia).
- an increase in liver enzymes
- positive Coomb's test

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. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of CEFUGEN.

5. How to store CEFUGEN

Store all medicines out of reach of children.

Store at or below 25 °C.

This medicinal product does not require any special storage conditions.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information**What CEFUGEN contains****CEFUGEN 250:**

The active substance is cefuroxime (cefuroxime axetil).

CEFUGEN 500:

The active substance is cefuroxime (cefuroxime axetil).

The other ingredients are microcrystalline cellulose, croscarmellose sodium, sodium lauryl sulfate, colloidal anhydrous silica, hydrogenated vegetable oil, hypromellose, titanium dioxide, macrogol 400 and purified water.

What CEFUGEN looks like and contents of the pack

CEFUGEN 250 are white to off-white, film coated, capsule shaped tablets with 'A 33' debossed on one side and plain on the other side.

They are packaged in aluminium blister packs, enclosed in a carton containing 10 tablets.

CEFUGEN 500 are white to off-white, film coated, capsule shaped tablets with 'A 34' debossed on one side and plain on the other side.

They are packaged in aluminium blister packs, enclosed in a carton containing 10 tablets.

Holder of Certificate of Registration

Unimed Healthcare (Pty) Ltd
Corner Birch Road & Bluegum Avenue,
Anchorville,
Lenasia, 1827

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