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APPROVED
By Keshmika Narain at 10:09 am, Oct 29, 2025

CEFALEXIN AURO P1540581

CEFALEXIN AURO P1540581

PROFFESSIONAL INFORMATION

SCHEDULING STATUS
SOUTH AFRICA: S4
NAMIBIA: NS2

PROPRIETARY NAME (and dosage form)
CEFALEXIN 500 mg AURO (tablet)

COMPOSITION
CEFALEXIN 500 mg AURO: Each capsule contains cefalexin monohydrate equivalent to anhydrous cefalexin 500 mg. The other ingredients contained in **CEFALEXIN AURO** are: cellulose microcrystalline, magnesium stearate and sodium starch glycolate. The coating material contains glycerol, hypromellose, talc, titanium dioxide (C.I. No: 77891), iron oxide red (C.I. No: 77491) and iron oxide yellow (C.I. No: 77492).
Sugar free.

PHARMACOLOGICAL CLASSIFICATION
A.20.1.1 Broad and medium spectrum antibiotics

PHARMACOLOGICAL ACTION
Cefalexin inhibits bacteria cell wall synthesis, probably by acylation of the membrane-bound enzyme transpeptidase. This prevents cross-linkage of peptidoglycan chains which is necessary for bacterial cell wall strength and rigidity. Cell division and growth are also inhibited and lysis of susceptible bacteria frequently occurs.
Cefalexin is almost completely absorbed from the gastrointestinal tract and produces peak plasma concentrations about 1 hour after oral administration. A dose of 500 mg produces peak plasma concentration of about 16 µg/ml; doubling the dose doubles the peak plasma concentration.
Absorption may be delayed with the intake of food. About 90 % or more of the dose is excreted unchanged in the urine within 8 hours.
Cefalexin is active in vitro against both Gram-positive and Gram-negative micro-organisms (in-vitro sensitivity does not necessarily imply in vivo efficacy). Group A *Streptococcus pyogenes*, the viridans group, and non-haemolytic streptococci, *Streptococcus (D) pneumonia*, penicillin-resistant and penicillin-sensitive *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Clostridium perfringens*, *B. subtilis*, *C. diphtheria*, *N. gonorrhoea*, *N. meningitides* and *A. isreali* are highly to this agent, many being suppressed by concentration of 0,004 to 1 µg/ml.
Gram-negative bacteria are generally less susceptible or resistant, including the following strains of Salmonella, including *S. typhi*, most Shigella, all *P. mirabilis*, and about 75 % of E.coli, 60 % of paracolon strains are inhibited by 1 to 6 µg/ml. Indole-producing strains of *Proteus Enterobacter (Aerobacter)* Pseudomonas, and an occasional strain of Klebsiella are highly resistant to Cefalexin. Enterococci and *H. influenza* are also insensitive to the medicine. Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Cefalexin.

INDICATIONS
CEFALEXIN AURO is indicated for the treatment of the following infections due to susceptible micro-organisms:
- Respiratory tract infections caused by *Streptococcus pneumoniae* and group A β-haemolytic streptococci.
- Otitis media due to *Streptococcus pneumoniae*, *H. influenzae*, staphylococci, streptococci and *N. catarrhalis.*
- Dental infections caused by staphylococci and/or streptococci.
- Skin and soft-tissue infections caused by staphylococci and/or streptococci.

CONTRAINDICATIONS
Patients with known or suspected hypersensitivity to cephalosporin or penicillin should not be treated with **CEFALEXIN AURO.**
Pregnancy and lactation (see **"PREGNANCY AND LACTATION"**)

WARNINGS AND SPECIAL PRECAUTIONS
CEFALEXIN AURO should be used with caution in patients with a history of gastrointestinal disease, especially ulcerative colitis, regional enteritis or antibiotic-associated colitis. The diagnosis of pseudomembranous colitis must be considered in patients who develop diarrhoea in association with its use. Such colitis may be life-threatening and appropriate measures should be taken, including discontinuation of **CEFALEXIN AURO.**
Care is necessary in treating patients known to be hypersensitive to cephalosporins and penicillin or with known histories of allergy.
CEFALEXIN AURO should be given cautiously to penicillin-sensitive patients as cross sensitivity may exist.
Patients should be carefully observed, so that any side-effects or unusual manifestations of medicine idiosyncrasy may be detected. If an allergic reaction to **CEFALEXIN AURO** occurs, the medicine should be discontinued and the patient treated with usual agents, e.g. adrenaline/epinephrine, aminophylline, corticosteroids and/or antihistamines. Prolonged used of **CEFALEXIN AURO** may result in the overgrowth of non-susceptible organisms. Careful observation of the patient is therefore essential. If superinfection occurs during therapy, appropriate measures should be taken.
CEFALEXIN AURO should be administered with caution in the presence of impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than usually recommended.

INTERACTIONS
There have been reports of **CEFALEXIN AURO** decreasing the efficacy of oestrogen containing oral contraceptives. The potential for increased nephrotoxicity exist when **CEFALEXIN AURO** is used with other nephrotoxic medications, such as loop diuretics (e.g. furosemide, ethacrynic acid) and aminoglycosides especially in patients with pre-existing renal functions impairment.

PREGNANCY AND LACTATION
Pregnancy: **CEFALEXIN AURO** crosses the placenta.
Safety of this product for use during pregnancy and lactation has not been established.
Breast feeding: **CEFALEXIN AURO** is excreted in breast milk.

DETACH BEFORE DISPENSING

If you take more CEFALEXIN AURO than you should:
- Seek emergency medical attention if you think you have used too much of this medicine.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take CEFALEXIN AURO:
Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

5. POSSIBLE SIDE EFFECTS
CEFALEXIN AURO can have side effects.
Get emergency medical help at once if you have any of these signs of an allergic reaction:
- Hives
- Difficulty breathing
- Swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have any of these serious side effects:
- Diarrhoea that is severe, watery or bloody, severe stomach cramps
- Fever
- Skin rashes which may be itchy
- Skin rash with joint pain and fever
- Easy bruising or bleeding, unusual weakness
- Fever, chills, body aches, flu symptoms
- Seizure (black-out or convulsions)
- Yellowing eyes/skin
- Confusion, agitation, hallucinations (seeing things that are not there)

Other side-effects include: feeling sick (nausea); vomiting; mild diarrhoea; abdominal pain; indigestion; vaginal itching or discharge; headache; dizziness; tiredness; abnormal liver tests.
Tell your doctor if any of the above side-effects are severe, bothersome, or if you have any concerns you have while taking **CEFALEXIN AURO**.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF CEFALEXIN AURO

Store all medicines out of the reach of children.

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

Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF CEFALEXIN AURO
CEFALEXIN 500 mg AURO:
1. PVC-Aluminium blister packaging:
Tablets are packed in 250 µm clear PVC film as the forming material and 25 µm printed aluminium foil as the lidding material. Each blister contains 10 tablets.
Pack size: 20s: Each carton contains 2 blisters of 10 tablets each.
100s: Each carton contains 10 blisters of 10 tablets each.
2. PVC/PVdc-Aluminium blister packaging:
Tablets are packed in clear 250 µm PVC film-coated with 60 g/m2 PVdc as the forming material and 25 µm printed aluminium foil as the lidding material. Each blister contains 10 tablets.
Pack size: 20s: Each carton contains 2 blisters of 10 tablets each.
100s: Each carton contains 10 blisters of 10 tablets each.

8. IDENTIFICATION OF CEFALEXIN AURO
CEFALEXIN 500 mg AURO: Peach coloured capsule shaped film coated tablets debossed with 'A' on one side and with a score line in between '4' and '0' on the other side.

9. REGISTRATION NUMBERS/REFERENCE NUMBERS
SOUTH AFRICA:
CEFALEXIN 500 mg AURO: 41/20.1.1/0388
NAMIBIA:
CEFALEXIN 500 mg AURO: 10/20.1.1/0437

10. NAME AND ADDRESS OF REGISTRATION HOLDER OF REGISTRATION
Aurogen South Africa (Pty) Ltd.
Woodhill Office Park, Building 1, First floor,
53 Phillip Engelbrecht Avenue,
Meyersdal, Ext. 12, 1448,
Johannesburg,
South Africa.

11. DATE OF PUBLICATION
12 June 2009
Date of revision:
25 March 2025

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS
SOUTH AFRICA: S4
NAMIBIA: NS2

CEFALEXIN 500 mg AURO (tablets)
Cefalexin monohydrate
Sugar free.

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **CEFALEXIN AURO** 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.

1. WHAT CEFALEXIN AURO CONTAIN
The active substance is cefalexin.
CEFALEXIN 500 mg AURO:
Each film-coated tablet contains cefalexin monohydrate equivalent to anhydrous cefalexin 500 mg.
The other ingredients contained in **CEFALEXIN AURO** are: cellulose microcrystalline, magnesium stearate and sodium starch glycolate. The coating material contains glycerol, hypromellose, talc, titanium dioxide (C.I. No: 77891), iron oxide red (C.I. No: 77491) and iron oxide yellow (C.I. No: 77492).

2. WHAT CEFALEXIN AURO ARE USED FOR
CEFALEXIN AURO contain the active ingredient cefalexin. Cefalexin is an antibiotic belonging to the cephalosporin class.
Cefalexin is used to treat bacterial infections.
Cefalexin works by interfering with the ability of bacteria to form cell walls. The cell walls of bacteria are vital for their survival. Cefalexin impairs the bonds that hold the bacterial cell wall together. This allows holes to appear in the cell walls and kills the bacteria.
CEFALEXIN AURO is used to treat a wide variety of bacterial infections, including infections of the lungs and airways, middle ear, teeth or gums and skin or soft tissue.

3. BEFORE YOU TAKE CEFALEXIN AURO
Do not take CEFALEXIN AURO:
- If you have ever had an allergic reaction to this medicine, to any other cephalosporin antibiotic, or to a penicillin antibiotic.
- If you are pregnant or breastfeeding.

Take special care with CEFALEXIN AURO:
- **CEFALEXIN AURO** may cause a severe intestinal condition called pseudomembranous colitis. Tell your doctor immediately if stomach pain or cramps, severe or watery diarrhoea, or bloody stools occur.
- If you experience any allergic symptoms while you are taking **CEFALEXIN AURO** and contact your doctor immediately. Get emergency help if you have any of these signs of a serious allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue or throat.
- Use of **CEFALEXIN AURO** may result in an infection that occurs while you are being treated for an infection. Tell your doctor if signs of a second infection occur.

Before using **CEFALEXIN AURO**, tell your doctor if you:
- have a history of stomach/intestinal disease e.g. colitis (inflammation of the colon).
- suffer from kidney problems. Your doctor may need to reduce your dosage.

Pregnancy and Breastfeeding:
- The safety of **CEFALEXIN AURO** in pregnancy and breastfeeding has not been determined.

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Taking other medicines with CEFALEXIN AURO:
Some medicines may interact with cefalexin. Before taking **CEFALEXIN AURO**, tell your doctor if you are using any of the following medicines:
- Oral contraceptives – Your oral contraceptive may not work properly. This can result in pregnancy. You will need to use extra contraceptive precautions, such as using a condom. If you need any advice, talk to your doctor or pharmacist.
- Aminoglycosides (e.g. gentamycin) or diuretics/water pills (e.g. furosemide, ethacrynic acid) – The risk of toxic effects on the kidneys may be increased.

If you are using any of these medicines, you may not be able to take **CEFALEXIN AURO**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side effects.

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

4. HOW TO TAKE CEFALEXIN AURO
- **CEFALEXIN AURO** are to be taken by mouth.
- **CEFALEXIN AURO** are not suitable for children.
- Your doctor will decide what dose and how long you will receive **CEFALEXIN AURO**. This will depend on the type and severity of infection. The dose varies from patient to patient.
- The dose of **CEFALEXIN AURO** for adults ranges from 1 g to 4 g in divided doses.
- The dosing interval may be every 6 or 12 hours depending on the infection.
- The usual adult dose is one 250 mg tablet taken every 6 hours. Your doctor may recommend a different dose depending on your condition.
- Keep taking **CEFALEXIN AURO** for the full time of treatment, even if you begin to feel better after a few days. If you do not complete the full course prescribed by your doctor, your infection may not clear completely or your symptoms may return.

Always take **CEFALEXIN AURO** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **CEFALEXIN AURO** is too strong or too weak, talk to your doctor or pharmacist.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS
SUID AFRIKA: S4
NAMIBIË: NS2

CEFALEXIN 500 mg AURO (tablet)
Kefaleksienmonohidraat
Suikervry.

Lees die hele brosjure sorgvuldig voordat u begin om te neem
- Hou hierdie blaadjie. U mag dit moontlik weer wil lees.
- Indien u enige verdere vrae het, moet u asseblief u dokter of apteker raadpleeg.
- **CEFALEXIN AURO** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense te deel nie. Dit mag hulle skade aandoen, ookal het hulle dieselfde simptome as u.

1. WAT CEFALEXIN AURO BEVAT

Die aktiewe bestanddeel is kefaleksien.
Elke tablet bevat kefaleksienmonohidraat ekwivalent aan 500 mg anhidriese kefaleksien.
Die ander bestanddele in **CEFALEXIN AURO** is: mikrokristallyne sellulose, magnesiumstearaat en natriumstyselglikolaat. Die dekmateriaal bevat gliserol, hipromellose, talk, titaandioksied (C.I. Nr. 77891), ysteroksied rooi (C.I. Nr. 77491) en ysteroksied geel (C.I. Nr. 77492).

2. WAARVOOR CEFALEXIN AURO GEBRUIK WORD

CEFALEXIN AURO bevat die aktiewe bestanddeel kefaleksien. Kefaleksien is 'n antibiotika wat aan die klas kefalosporiene behoort. Kefaleksien word gebruik om infeksies wat deur bakterieë veroorsaak word, te behandel.

Kefaleksien werk deur in te meng met die vermoë van bakterieë om selwande te vorm. Die selwande van bakterieë is noodsaaklik vir hul oorlewing. Kefaleksien verswak die bande wat die bakteriese selwand bymekaar hou. Dit veroorsaak dat gaatjies in die selwand ontwikkel en die bakterie afsterf.

CEFALEXIN AURO word gebruik om 'n groot verskeidenheid bakteriese infeksies te behandel, insluitende infeksies van die longe en lugweg, middeloor, tande of tandvleis en vel of sagteweefsel.

3. VOORDAT U CEFALEXIN AURO NEEM

Moenie CEFALEXIN AURO neem nie:
- As u ooit 'n allergiese reaksie teen hierdie medisyne of enige ander kefalosporien gehad het.
- As u swanger is of borsvoed.

Neem spesiale sorg met :
- **CEFALEXIN AURO** kan 'n ernstige intestinale kondisie pseudomembraneuse kolitis veroorsaak. Stel u dokter onmiddellik in kennis as maagpyn of -krampe, erge of waterige diaree of bloederige stoelgang voorkom.
- As u enige allergiese simptome ontwikkel terwyl u **CEFALEXIN AURO** neem. Staak met die gebruik van **CEFALEXIN AURO** en raadpleeg onmiddellik u dokter. Kry nood mediese behandeling as u enige van hierdie tekens van 'n ernstige allergiese reaksie toon: urtikarie, moeite met asemhaling, swelling van u gesig, lippe, tong of keel.
- Die gebruik van **CEFALEXIN AURO** kan tot 'n infeksie lei terwyl u vir 'n infeksie behandel word. Stel u dokter in kennis as 'n tweede infeksie voorkom.

Voordat u bergin om **CEFALEXIN AURO** te gebruik moet u u dokter in kennis stel:
- As u 'n geskiedenis van maag/intestinale siekte het bv. kolitis (inflammasie van die kolon).
- As u aan nierprobleme lei. Dit mag vir u dokter nodig wees om die dosis te verminder.

Swangerskap en borsvoeding:
- Die veiligheid van **CEFALEXIN AURO** gedurende swangerskap en laktasie is nie vasgestel nie.

As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander gesondheidsbeampte vir advies nader voordat u **CEFALEXIN AURO** neem.

Die neem van ander medisyne saam met :
Sommige medisyne kan 'n interaksie met kefaleksien toon. Voordat u begin om **CEFALEXIN AURO** te neem, moet u u dokter in kennis stel as u enige van die volgende medisyne gebruik:
- Orale voorbehoedmiddels - u orale voorbehoedmiddel mag moontlik nie behoorlik werk nie. Dit kan tot swangerskap lei. U sal addisionele voorbehoedende maatreëls soos 'n kondoom moet gebruik. As u enige advies nodig het moet u u dokter of apteker raadpleeg.
- Aminoglukosiede (bv. gentamisien) diuretika/waterpille (bv. furosemied, etakriensuur) - die risiko van toksiese effekte op die niere kan toeneem.

As u enige van hierdie medisyne neem, sal u moontlik nie **CEFALEXIN AURO** kan gebruik nie, of u mag 'n dosisaanpassing benodig of dit mag nodig wees dat u dokter u noukeurig vir newe effekte monitor.

Stel altyd u professionele gesondheidswerker in kennis as u enige ander medisyne gebruik.
(Dit sluit komplementêre en tradisionele medisyne in).

4. HOE OM CEFALEXIN AURO TE NEEM

- **CEFALEXIN AURO** moet oraal geneem word.
- **CEFALEXIN AURO** is nie geskik vir kinders nie.
- U dokter sal op die dosis besluit en vir hoelank u **CEFALEXIN AURO** moet gebruik. Dit sal van die tipe en graad van erns van die infeksie afhang. Die dosis wissel van een pasiënt na die volgende.
- Die dosis van **CEFALEXIN AURO** vir volwassenes wissel van 1 g tot 4 g in verdeelde dosisse.
- Die dosisinterval kan afhangende van die infeksie elke 6 tot 12 wees.
- Die normale volwasse dosis is 250 mg elke 6 ure. Afhangende van u kondisie kan u dokter egter 'n ander dosis voorstel.
- Hou aan om die **CEFALEXIN AURO** vir die volle tydperk van behandeling te neem, selfs al begin u na 'n paar dae reeds beter voel. Indien u nie die volle kursus wat deur u dokter voorgeskryf is neem nie, mag die infeksie nie volledig opgeklaar word nie of die simptome kan terugkeer.

Neem **CEFALEXIN AURO** altyd presies soos deur u dokter voorgeskryf. Bevestig met u dokter of apteker as u onseker is. As u van mening is dat die effek van **CEFALEXIN AURO** te sterk of te swak is, moet u u dokter of apteker raadpleeg.

As u te veel CEFALEXIN AURO geneem het:
- Kry nood mediese hulp as u dink dat u te veel van hierdie medisyne geneem het.

In die geval van oordosering, raadpleeg u dokter of apteker. As hulle nie beskikbaar is nie, kontak u naaste hospitaal of gifbeheersentrum.

As u vergeet het om CEFALEXIN AURO te neem:
Neem die oorgeslaande dosis sodra u daarvan onthou. As dit egter byna tyd vir die volgende dosis is, slaan die oorgeslaande dosis oor en gaan met die gereelde doseringskedule voort. Moenie 'n dubbel dosis neem om vir 'n oorgeslaande dosis op te maak nie.

5. MOONTLIKE NEWE EFFEKTE

CEFALEXIN AURO kan newe effekte hê.
Kry onmiddellik nood mediese hulp as u enige van hierdie tekens van 'n allergiese reaksie ondervind:
- Korwe.
- Moeite met asemhaling.
- Swelling van u gesig, lippe, tong of keel.

Raadpleeg onmiddellik u dokter as u enige van hierdie ernstige newe effekte ondervind:
- Erge, waterige, bloederige diaree.
- Koors.
- Veluitslag met jeuk.
- Veluitslag met gewrigspyn en koors.
- Maklike kneusing of bloeding, ongewone swakheid.
- Koors, kouekoors, liggaamspyn, griepsimptome.
- Stuipaanvalle (bewusteloosheid of stuiptrekkings).
- Geel verkleuring van die oë/vel.
- Verwardheid, agitasie, hallusinasies (sien dinge wat nie daar is nie).

Ander newe effekte sluit die volgende in: Naarheid, braking, matige diaree, buikpyn, indigestie, vaginale jeuk of uitskeiding, hoofpyn, duiseligheid, moegheid, abnormale lewertoetse.

Stel u dokter so gou as moontlik in kennis as enige van die bogenoemde newe effekte erg of kwellend is, of as hulle nie verdwyn nie of as u enige besorgdheid het terwyl u **CEFALEXIN AURO** neem.

Nie al die newe effekte wat vir **CEFALEXIN AURO** aangemeld is, word in hierdie brosjure ingesluit nie. As u algemene gesondheid agteruitgaan of as u enige ongewone effekte ondervind terwyl u **CEFALEXIN AURO** neem, moet u asseblief u dokter, apteker of ander professionele gesondheidswerker om advies raadpleeg.

6. OPBERGING EN WEGDOEN VAN

Berg alle medisyne buite die bereik van kinders.

Bewaar teen of benede 25 °C (kamertemperatuur).

Neem alle ongebruikte medisyne na u apteker terug.
Moenie enige ongebruikte medisyne in die drein of riolering (bv. toilette) weggooi nie.

7. AANBIEDING VAN CEFALEXIN AURO

CEFALEXIN 500 mg AURO:

1. PVC/Aluminium stolpverpakking:
Tablette word in 250 mikron PVC film as die vormingsmateriaal en 25 mikron gedrukte aluminiumfoelie as dekmateriaal verpak. Elke stolpstrokie bevat 10 tablette.
Pakgrootte: 20s – Elke karton bevat 2 stolpstrokies met 10 tablette elk.
100s – Elke karton bevat 10 stolpstrokies met 10 tablette elk.

2. PVC/PVdc –aluminium stolpverpakking:
Tablette word in helder 250 mikron PVC film bedek met 60 gvm PVdc as vormingsmateriaal en 25 mikron gedrukte aluminiumfoelie as die dekmateriaal verpak. Elke stolpstrokie bevat 10 tablette.
Pakgrootte: 20s – Elke karton bevat 2 stolpstrokies met 10 tablette elk
100s – Elke karton bevat 10 stolpstrokies met 10 tablette elk.

8. IDENTIFIKASIE VAN CEFALEXIN AURO

CEFALEXIN 500 mg AURO:
Perskekleurige, kapsulevormige, filmbedekte tablet met 'A' op die een kant en 'n breeklyn tussen die '4' en '0' op die ander kant gedruk.

9. REGISTRASIENOMMER / VERWYSINGSNOMMER

SUID AFRIKA:
CEFALEXIN 500 mg AURO: 41/20.1.1/0388
NAMIBIË:
CEFALEXIN 500 mg AURO: 10/20.1.1/0437

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER

Aurogen South Africa (Edms.) Bpk.
Woodhill Kantoorpark, Gebou 1, Eerste vloer,
Phillip Engelbrechtlaan 53,
Meyersdal, Uitbr. 12, 1448,
Johannesburg,
Suid Afrika.

11. DATUM VAN PUBLIKASIE

Datum van registrasie:
12 Junie 2009

Datum van hersiening:
25 Maart 2025

DOSAGE AND DIRECTIONS FOR USE
CEFALEXIN AURO are administered orally. This formulation is not suitable for children.
Adults: The adult dosage ranges from 1 g to 4 g in equally divided doses. The usual adult dosage is 250 mg every 6 hours. For skin and soft-tissue infections, streptococcal pharyngitis or tonsilitis and mild, uncomplicated urinary tract infections, a dosage of 500 mg may be administered every 12 hours. For more severe infections or those caused by less susceptible organisms, larger doses may be needed. Parenteral cephalosporin therapy, in appropriate doses, should be considered if daily doses higher than 4 g of **CEFALEXIN AURO** are required. In the treatment of beta-haemolytic streptococcal infections, antibiotics should continue for at least 10 days.

SIDE EFFECTS
Gastrointestinal disorders:
Frequent: Nausea, Diarrhoea, nausea, vomiting, abdominal pain.
Less frequent: Dyspepsia, colitis, including pseudomembranous colitis.

Immune system disorders:
Less frequent: Allergic reactions such as skin rashes, urticarial, anaphylaxis, drug fever, reactions resembling serum-sickness.
The following effects have been reported and frequencies are unknown: Angioedema.

Reproductive system and breast disorders
Frequent: Vaginal discharge.
Less Frequent: Genital and anal pruritus, vaginitis.
The following side effects have been reported and frequencies are unknown: *Genital moniliasis.*

Nervous system disorders:
Frequent: Headache.
Less frequent: Dizziness, fatigue, convulsions.
The following side-effects have been reported and frequencies are unknown: Toxic psychosis.

Blood and the lymphatic system disorders:
Frequent: Eosinophilia.
Less frequent: Neutropenia, thrombocytopenia, hepatitis, cholestatic jaundice.

Investigations:
The following side-effects have been reported and frequencies are unknown: Elevation in AST (aspartate-transaminase) and ALT (alanine-transaminase) have been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
(See "**SIDE EFFECTS**").
Serious acute hypersensitivity reactions may require adrenaline/epinephrine, aminophylline and corticosteroids, including other emergency measures.

IDENTIFICATION
CEFALEXIN 500 mg AURO:
Peach coloured capsule shaped film-coated tablets debossed with 'A' on one side and with a score line in between '4' and '0' on the other side.

PRESENTATION
CEFALEXIN 500 mg AURO:
1. PVC/ Aluminium blister packaging:
Tablets are packed in Clear 250 Micron Clear PVC Film as the forming material and 25 Micron Printed Aluminium Foil as the lidding material. Each blister contains 10 tablets each.
Pack size: 20s: Each carton contains 2 blisters of 10 tablets each.
100s: Each carton contains 10 blisters of 10 tablets each.

2. PVC/ PVdC- Aluminium blister packaging:
Tablets are packed in Clear 250 Micron PVC Film coated with 60 gsm PVdC as forming material and Micron Printed Aluminium Foil as the lidding material. Each blister contains 10 tablets.
Pack size: 20s: Each carton contains 2 blisters of 10 tablets each.
100s: Each carton contains 10 blisters of 10 tablets each

STORAGE INSTRUCTIONS
Store at or below 25 °C.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
SOUTH AFRICA:
CEFALEXIN 500 mg AURO: 41/20.1.1/0388
NAMIBIA:
CEFALEXIN 500 mg AURO: 10/20.1.1/0437

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Aurogen South Africa (Pty) Ltd.
Woodhill Office Park, Building 1, First floor,
53 Phillip Engelbrecht Avenue,
Meyerstdal, Ext. 12, 1448,
Johannesburg,
South Africa.

DATE OF PUBLICATION OF THE PACKAGE INSERT
12 June 2009
Date of revision:
25 March 2025

P1540581

AUROBINDO Packaging Development		Product Name	Component	Item Code	Date & Time
		Cefalexin 500 mg	Leaflet	P1540581	23.10.2025 & 05:50 PM
Team Leader	Kiran Kumar	Customer / Country	Version No.	Reason of Issue	No. of Colours : 1
Initiator	Bhogeswara Rao	Aurogen-South Africa-R1-U6	04	New	■ Black
Design Agency	vakils	Dimensions	Font Type	Font Size	
APL_LN: 3695		280 mm x 480 mm	Helvetica	8 pt	
		Pharmacode			
		40581			Reviewed / Approved by

Date - Designer - Run:
1. 17-SEP-2025 (Mayuri) - FR
2. 03-OCT-2025 (Mayuri) - RR1
3. 09-OCT-2025 (Dipali) - RR2
4. 14-OCT-2025 (Mayuri) - RR3
5. 23-OCT-2025 (Mayuri) - RR4
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7.

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Additional Information: Supercede Item Code-P1532399

Sign / Date