

Applicant: Aurogen South Africa (Pty) Ltd
Product Name: **CEFALEXIN 125 mg/5 mL SUSPENSION AURO and
CEFALEXIN SUSPENSION 250 mg/5 mL AURO**
Dosage form and strength: (powder for oral suspension),
Each 5 mL reconstituted suspension contains cephalexin monohydrate
equivalent to cephalexin 125 mg and 250 mg

MODULE 1
1.3.2
Date: 2021.07.06

1.3.2 Patient Information Leaflet

SCHEDULE STATUS

S4

PATIENT INFORMATION LEAFLET

CEFALEXIN SUSPENSION 125 mg/5ml AURO, 125mg/5ml (powder for oral suspension)

CEFALEXIN SUSPENSION 250 mg/5ml AURO, 250mg/5ml (powder for oral suspension)

Cephalexin

Contains sucrose:

CEFALEXIN SUSPENSION 125 mg/5ml AURO: 2550,066 mg/5 ml

CEFALEXIN SUSPENSION 250 mg/5ml AURO: 2418,590 mg/5 mL

**Read all of this leaflet carefully before you start taking CEFALEXIN SUSPENSION
AURO.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **CEFALEXIN SUSPENSION 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.

What is in this leaflet?

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

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1. What **CEFALEXIN SUSPENSION AURO** is and what it is used for?

CEFALEXIN SUSPENSION AURO contain a medicine called Cephalexin. This belongs to a group of antibacterial medicine.

CEFALEXIN SUSPENSION AURO is used to treat **Respiratory tract infections** (any infectious disease of the upper or lower), **Otitis media** (inflammation of the ear), **Skin and soft tissue infections** (microbial invasion of the layers of the skin and underlying soft tissues), **Genito-urinary tract infections** (infection in any part of your **urinary system**, which includes your kidneys, bladder, ureters, and urethra) and **Dental infections** (Mouth infections).

2. What you need to know before you take **CEFALEXIN SUSPENSION AURO**

Do not take **CEFALEXIN SUSPENSION AURO:**

- If you are allergic or sensitive to **CEFALEXIN SUSPENSION AURO** or any of the ingredients of **CEFALEXIN SUSPENSION AURO**
- If you are allergic to a group of antibiotics called cephalosporins
- If you are pregnant or breastfeeding

Tell your doctor or healthcare professional before taking **CEFALEXIN SUSPENSION AURO:**

- If you are a penicillin-sensitive patient (an allergy or sensitive to the antibiotic used to treat or prevent various infections).
- If you have impaired renal function (when your kidneys are not working as well as they should), a dosage reduction may be necessary. Especially in Elderly patient's, who are more likely to have decreased renal function, care should be taken in dose selection.

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- If you observe any diarrhoea while taking **CEFALEXIN SUSPENSION AURO**. Stop treatment immediately and discuss with your doctor.
- If you have kidney function condition.
False high values of creatinine concentrations may be produced.
- If you are taking medication to treat a condition whereby blood is taking too **long** to form a clot. Use of taking **CEFALEXIN SUSPENSION AURO** may affect the clotting time further.
This may also be seen in patients with reduced kidney or liver function.

Other medicines and CEFALEXIN SUSPENSION AURO

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

CEFALEXIN SUSPENSION AURO may have an effect on other medicines or other medicines may have an effect on **CEFALEXIN SUSPENSION AURO**

- Combination of **CEFALEXIN SUSPENSION AURO** and medicines such as aminoglycosides (antibiotics used to treat severe infections of the abdomen and urinary tract) may cause further damage to the kidneys.
- Taking of probenecid with cephalexin is not recommended. The release of **CEFALEXIN SUSPENSION AURO** from kidney is prevented.
- Taking **CEFALEXIN SUSPENSION AURO** with metformin may require a dose adjustment of metformin.
- There may be antagonism between **CEFALEXIN SUSPENSION AURO** and bacteriostatic anti-bacterials.
- **CEFALEXIN SUSPENSION AURO** may decrease the effectiveness of oestrogen containing contraceptives.

Taking CEFALEXIN SUSPENSION AURO with food and drink:

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CEFALEXIN SUSPENSION AURO can be taken before or after meals.

Pregnancy and breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **CEFALEXIN SUSPENSION AURO**.

The safety in pregnancy and lactation has not been established. You should not take **CEFALEXIN SUSPENSION AURO** if you are pregnant.

Breastfeeding

CEFALEXIN SUSPENSION AURO is given off in breast milk. You should not take **CEFALEXIN SUSPENSION AURO** if you are breastfeeding.

Effects on Men

No known effect

Driving and using machinery:

CEFALEXIN SUSPENSION AURO can cause dizziness and drowsiness. In that case, the patient is not allowed to drive or operate machines until the symptoms disappear.

Important information about some of the ingredients of CEFALEXIN SUSPENSION AURO

CEFALEXIN SUSPENSION AURO contains sucrose: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take CEFALEXIN SUSPENSION AURO

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

Always take **CEFALEXIN SUSPENSION AURO** exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure. Your doctor will tell you how long your treatment with **CEFALEXIN SUSPENSION AURO** will last. If you have the impression that the effect of **CEFALEXIN SUSPENSION AURO** is too strong or too weak, talk to your doctor or pharmacist.

Adult dose:

The adult dosage ranges from 1-4 g daily in divided doses.

The **usual adult dosage** is 250 mg every 6 hours.

For **skin and soft tissue infections:** usual dosage is 250 mg every 6 hours, or 500 mg every 12 hours.

Adults who are not able to take capsules may be given **CEFALEXIN SUSPENSION AURO**.

For **more severe infections:** larger doses may be needed.

If daily doses of **CEFALEXIN SUSPENSION AURO**, greater than 4 grams are required, injectable cephalosporins, in appropriate doses, should be considered.

Children:

The **usual** recommended dosage for children is 25 mg/kg/day to 50 mg/kg/day in divided doses every six hours.

In the **treatment of beta-haemolytic streptococcal** infections (type of bacteria that grow in culture as pairs or chains), a therapeutic dose should be administered for at least 10 days.

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Your doctor will tell you how long your treatment with **CEFALEXIN SUSPENSION AURO** will last. Do not stop treatment early because this may reoccurrence of your condition. If you have the impression that the effect of **CEFALEXIN SUSPENSION AURO** is too strong or too weak, tell your doctor or pharmacist.

If you take more CEFALEXIN SUSPENSION AURO than you should:

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

Symptoms of Overdose

Symptoms of oral overdose may include nausea, vomiting, pain to the upper tummy are immediately below the ribs, diarrhoea, and blood in the urine. In the event of an overdose, institute general supportive measures.

If you forget to take CEFALEXIN SUSPENSION AURO:

If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

CEFALEXIN SUSPENSION AURO can have side effects.

Not all side effects reported for **CEFALEXIN SUSPENSION AURO** 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.

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

- Hypersensitivity reactions including anaphylaxis (an allergic reaction to which the body has become hypersensitive.)
- Anaphylaxis - a severe, life-threatening allergic reaction

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- Rash or itching
 - Reactions resembling serum sickness-like reactions - immune response that's similar to an allergic reaction. It happens when certain medication cause the immune system to react.
- These are all very serious side effects. If you have them, you may have had a serious reaction to **CEFALEXIN SUSPENSION AURO**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

The following side effects occur frequently:

- Eosinophilia - increased number of disease-fighting white blood cell.
- Headache
- Nausea
- Vomiting
- Diarrhoea

The following side effects rarely occur:

- Haemolytic anaemia - a disorder in which red blood cells are destroyed faster than they can be made.
- Drug induced neutropenia - decrease in absolute neutrophil counts due to exposure to a medicine.
- Thrombocytopenia - when medicines are the causes of a low platelet count, these cells help blood to clot, hence bleeding is more likely.
- Fever
- Dizziness
- Drowsiness.
- Confusion
- Seizures

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- Stomach cramps
- Hepatitis - inflammatory condition of the liver.
- Cholestatic jaundice - impairment in bile formation and/or bile flow.
- Nephrotoxicity - It is a poisonous effect of some substances on kidney function.
- Acute renal tubular necrosis - kidney disorder involving damage to the tubule cells of the kidneys, which can lead to acute kidney failure.
- Acute Interstitial nephritis - kidney condition characterized by swelling in between the kidney tubules.
- Vulval candidiasis – vaginal infection
- Tiredness

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via https://www.sahpra.org.za/documents/86422f1b6.04_ARF1_Jul16_v4.pdf. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store CEFALEXIN SUSPENSION AURO

For Dry powder:

Store between at or below 25 °C (15 °C to 25 °C).

Protect from light.

For Reconstituted suspension:

The reconstituted suspension is stable for 14 days under refrigeration (2 – 8 °C)

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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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 CEFALEXIN SUSPENSION AURO contains

The active substance is cephalexin monohydrate.

The other ingredients of **CEFALEXIN SUSPENSION AURO** are:

- Sucrose USNF (40/80)
- Silicon Dioxide USNF (Syloid AL-1-FP)
- Sodium Benzoate USNF
- Xanthan Gum USNF (Xantural 75)
- Art Cherry Flavour IHS (SD #594)
- FD&C Red No. 40 HIS

What CEFALEXIN SUSPENSION AURO looks like and contents of the pack

CEFALEXIN SUSPENSION 125 mg/5 ml AURO, (powder for oral suspension)

CEFALEXIN SUSPENSION 250 mg/5 ml AURO, (powder for oral suspension)

Dry Powder:

Off-white to pale yellow coloured powder.

Reconstituted Suspension:

Off-white to light pink suspension with Cherry flavour

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HDPE Container Pack:

100 mL pack:

CEFALEXIN SUSPENSION AURO is a dry powder filled in heavy weight translucent round
150 ml HDPE container with 28 mm neck finish closed with white polypropylene 28 mm - 400
child resistant closure with universal induction sealing wad.

These Cephalexin for Oral Suspension USP HDPE bottles shall be further packed in pre-
printed carton with a packaging leaflet.

Holder of Certificate of Registration

AUROGEN SOUTH AFRICA (PTY) Ltd
Woodhill Office Park, Building 1
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448
Johannesburg
South Africa

This leaflet was last revised in

To be allocated

Registration Number

To be allocated