

Applicant: Aurogen South Africa (Pty) Ltd
Product Name: XENARA ORAL SUSPENSION 125 mg/5 mL and
XENARA ORAL SUSPENSION 250 mg/5 mL
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

XENARA ORAL SUSPENSION 125 mg/5ml, 125mg/5ml (powder for oral suspension)

XENARA ORAL SUSPENSION 250 mg/5ml, 250mg/5ml (powder for oral suspension)

Cephalexin

Contains sucrose:

XENARA ORAL SUSPENSION 125 mg/5ml: 2550,066 mg/5 ml

XENARA ORAL SUSPENSION 250 mg/5ml: 2418,590 mg/5 mL

Read all of this leaflet carefully before you start taking XENARA ORAL SUSPENSION.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **XENARA ORAL SUSPENSION** 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 **XENARA ORAL SUSPENSION** is and what it is used for
2. What you need to know before you use **XENARA ORAL SUSPENSION**
3. How to use **XENARA ORAL SUSPENSION**
4. Possible side effects
5. How to store **XENARA ORAL SUSPENSION**
6. Contents of the pack and other information

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1. What XENARA ORAL SUSPENSION is and what it is used for?

XENARA ORAL SUSPENSION contain a medicine called Cephalexin. This belongs to a group of antibacterial medicine.

XENARA ORAL SUSPENSION 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 XENARA ORAL SUSPENSION

Do not take XENARA ORAL SUSPENSION:

- If you are allergic or sensitive to **XENARA ORAL SUSPENSION** or any of the ingredients of **XENARA ORAL SUSPENSION**
- 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 XENARA ORAL SUSPENSION:

- 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.
- If you observe any diarrhoea while taking **XENARA ORAL SUSPENSION**. Stop treatment immediately and discuss with your doctor.
- If you have kidney function condition.

False high values of creatinine concentrations may be produced.

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- If you are taking medication to treat a condition whereby blood is taking too **long** to form a clot. Use of taking **XENARA ORAL SUSPENSION** may affect the clotting time further.

This may also be seen in patients with reduced kidney or liver function.

Other medicines and XENARA ORAL SUSPENSION

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

XENARA ORAL SUSPENSION may have an effect on other medicines or other medicines may have an effect on **XENARA ORAL SUSPENSION**

- Combination of **XENARA ORAL SUSPENSION** 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 **XENARA ORAL SUSPENSION** from kidney is prevented.
- Taking **XENARA ORAL SUSPENSION** with metformin may require a dose adjustment of metformin.
- There may be antagonism between **XENARA ORAL SUSPENSION** and bacteriostatic anti-bacterials.
- **XENARA ORAL SUSPENSION** may decrease the effectiveness of oestrogen containing contraceptives.

Taking XENARA ORAL SUSPENSION with food and drink:

XENARA ORAL SUSPENSION 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

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healthcare professional for advice before taking **XENARA ORAL SUSPENSION**.

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

Breastfeeding

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

Effects on Men

No known effect

Driving and using machinery:

XENARA ORAL SUSPENSION 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 XENARA ORAL SUSPENSION

XENARA ORAL SUSPENSION 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 XENARA ORAL SUSPENSION

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

Always take **XENARA ORAL SUSPENSION** 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 **XENARA ORAL SUSPENSION** will last. If you have the impression that the effect of **XENARA ORAL SUSPENSION** is too strong or too weak, talk to your doctor or pharmacist.

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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 **XENARA ORAL SUSPENSION**.

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

If daily doses of **XENARA ORAL SUSPENSION**, 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.

Your doctor will tell you how long your treatment with **XENARA ORAL SUSPENSION** will last.

Do not stop treatment early because this may reoccurrence of your condition. If you have the impression that the effect of **XENARA ORAL SUSPENSION** is too strong or too weak, tell your doctor or pharmacist.

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If you take more XENARA ORAL SUSPENSION 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 XENARA ORAL SUSPENSION:

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

XENARA ORAL SUSPENSION can have side effects.

Not all side effects reported for **XENARA ORAL SUSPENSION** 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 **XENARA ORAL SUSPENSION** 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
- 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.

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These are all very serious side effects. If you have them, you may have had a serious reaction to **XENARA ORAL SUSPENSION**. 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
- 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.

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- 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 XENARA ORAL SUSPENSION

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.

Return all unused medicine to your pharmacist.

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

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6. Contents of the pack and other information

What XENARA ORAL SUSPENSION contains

The active substance is cephalexin monohydrate.

The other ingredients of XENARA ORAL SUSPENSION 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
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What XENARA ORAL SUSPENSION looks like and contents of the pack

XENARA ORAL SUSPENSION 125 mg/5 ml, (powder for oral suspension)

XENARA ORAL SUSPENSION 250 mg/5 ml, (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:

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XENARA ORAL SUSPENSION 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
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53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448
Johannesburg
South Africa

This leaflet was last revised in

To be allocated

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