



**Applicant:** Pharmacare Ltd  
**Product name:** XIXIA-FLUCLOXACILLIN 250  
XIXIA-FLUCLOXACILLIN S  
**Dosage form and strength:** Each capsule contains 250 mg flucloxacillin  
Each 5ml of suspension contains 125 mg flucloxacillin

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### 1.3.2 Patient Information Leaflet

#### SCHEDULING STATUS

**S4**

**XIXIA-FLUCLOXACILLIN 250 250 mg capsules**

**Sugar free**

**Flucloxacillin**

**XIXIA-FLUCLOXACILLIN S 125 mg/5 ml powder for suspension**

**Contains sugar: Sucrose 3,332 mg per 5 ml**

**Contains sweetener: Saccharin sodium 15,8 mg per 5 ml**

**Flucloxacillin**

#### **Read all of this leaflet carefully before you start taking XIXIA-FLUCLOXACILLIN**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- XIXIA-FLUCLOXACILLIN 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 XIXIA-FLUCLOXACILLIN is and what it is used for

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2. What you need to know before you take XIXIA-FLUCLOXACILLIN
3. How to take XIXIA-FLUCLOXACILLIN
4. Possible side effects
5. How to store XIXIA-FLUCLOXACILLIN
6. Contents of the pack and other information

### **1. What XIXIA-FLUCLOXACILLIN is and what it is used for**

XIXIA-FLUCLOXACILLIN belongs to a group of medicines called penicillins.

- XIXIA-FLUCLOXACILLIN contains the active substance called flucloxacillin and is used to treat bacterial infections including:
  - Skin and soft tissue infections
  - Respiratory tract infections
  - Orthopaedic infections
  - Infected wounds and burns
  - Septicaemia (blood poisoning by bacteria)
  - Infection of the middle ear (otitis media)
  - Meningitis (a serious disease characterised by inflammation of the membranes around the brain or spinal cord)
  - Kidney, bladder or urethra (the tube which carries urine from the bladder)
  - Endocarditis (inflammation of the lining of the heart and its valves),
  - Enterocolitis (inflammation that occurs throughout the intestines).



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## 2. What you need to know before you take XIXIA-FLUCLOXACILLIN

### Do not take XIXIA-FLUCLOXACILLIN

- if you are hypersensitive (allergic) to flucloxacillin sodium or any of the other ingredients of XIXIA-FLUCLOXACILLIN (listed in section 6).
- if you have had an allergic reaction to beta-lactam antibiotics (e.g. penicillins, cephalosporins).
- if you have a previous history of flucloxacillin associated jaundice or hepatic dysfunction (liver problems).

### Warnings and precautions

Take special care with XIXIA-FLUCLOXACILLIN

- If you have a history of allergies and you are likely to develop an allergic reaction.
- cross allergy between penicillin and cephalosporins may occur.
- if you develop a rash with pinhead sized pustules, you should seek medical assistance immediately.
- if you have kidney problems, as you may require a lower dose than normal.
- if you suffer from liver problems, are at risk of liver problems, or develop liver problems.
- if you are you older than 50 years.
- if you are allergic to penicillins and your skin comes into contact with XIXIA-FLUCLOXACILLIN.



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- if you take XIXIA-FLUCLOXACILLIN over a long period, as you may experience an overgrowth of the natural organisms in your body, which may cause thrush infections.
- if you are taking this medicine for a long time as regular tests of liver and kidney function are advised.
- if you are taking or will be taking paracetamol.
- if you have other serious illness (apart from the infection this medicine is treating).
- if you will be receiving this medication on high dose as you may experience a decreased blood potassium level (hypokalaemia).

### **Children**

If you are giving this medicine to a newborn child they will need to be monitored closely by a doctor as this medicine can cause brain damage in a child with jaundice.

### **Other medicines and XIXIA-FLUCLOXACILLIN**

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

Tell your doctor if you are taking any of the following:

- probenecid or sulfapyrazone (used in the treatment of gout).
- piperacillin (an antibiotic used to treat infections).
- oral typhoid vaccine, as antibiotics can make this less effective.



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- methotrexate (a chemotherapy medicine), as you may experience severe side effects from the methotrexate.
- sugammadex (used in general anaesthetics).
- warfarin (medicine to prevent blood clotting), you will require careful monitoring by your doctor
- paracetamol
- other antibiotics (used to treat infections)
- voriconazole (used against fungal infections).

### **XIXIA-FLUCLOXACILLIN with food and drink**

Take XIXIA-FLUCLOXACILLIN one hour before meals.

### **Pregnancy, breastfeeding and fertility**

You should not take XIXIA-FLUCLOXACILLIN if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

### **Driving and using machines**

XIXIA-FLUCLOXACILLIN is not expected to influence your ability to drive. However, you should not drive, use machinery or perform any tasks that require concentration until you are certain that XIXIA-FLUCLOXACILLIN does not adversely affect your ability to do so safely.



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It is not always possible to predict to what extent XIXIA-FLUCLOXACILLIN may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which XIXIA-FLUCLOXACILLIN affects you.

### **XIXIA-FLUCLOXACILLIN contains sodium benzoate**

Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

### **XIXIA-FLUCLOXACILLIN 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 XIXIA-FLUCLOXACILLIN**

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

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

For oral use only.

Take this medicine when your stomach is empty. This means an hour before food.

### **Adults**

The usual dose of XIXIA-FLUCLOXACILLIN is 250 mg (1 capsule or 10 ml suspension) four times a day.



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- Skin and soft tissue infections up to 8 g daily in divided doses, six to eight hourly.

### **Use in children and adolescents**

Children 2 – 10 years:

The usual dose is 125 mg (5 ml suspension) four times a day preferably one hour before meals.

Children 2 months – 2 years:

The usual dose is 62,5 mg (2,5 ml suspension) four times a day preferably one hour before meals.

Your doctor will tell you how long your treatment with XIXIA-FLUCLOXACILLIN will last. Do not stop treatment early. If you have the impression that the effect of XIXIA-FLUCLOXACILLIN is too strong or too weak, tell your doctor or pharmacist.

### **If you take more XIXIA-FLUCLOXACILLIN 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 an overdose include feeling sick (nausea) and diarrhoea.



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### **If you forget to take XIXIA-FLUCLOXACILLIN**

Do not take a double dose to make up for forgotten individual doses. If you have missed a dose of XIXIA-FLUCLOXACILLIN, take the dose that you have missed as soon as you remember.

If you have forgotten to take several doses, contact your doctor without delay.

### **If you stop taking XIXIA-FLUCLOXACILLIN**

Do not stop treatment early because some bacteria may survive and cause the infection to come back. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

XIXIA-FLUCLOXACILLIN can have side effects.

Not all side effects reported for XIXIA-FLUCLOXACILLIN are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking XIXIA-FLUCLOXACILLIN, please consult your healthcare provider for advice.

If any of the following happens, stop taking XIXIA-FLUCLOXACILLIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,



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- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS) or acute generalised exanthematous pustulosis (AGEP).

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- fever, chills, swelling, sore throat, fatigue, which may be signs of an infection due to low white blood cell count (agranulocytosis, neutropenia),
- any unusual or unexplained bruising or bleeding due to a low blood platelet count (thrombocytopenia),
- an illness where you have a low number of red blood cells as they are being destroyed prematurely - this can make you feel very tired, breathless and dizzy and can give you headaches (haemolytic anaemia)
- painless swelling under the skin, such as the lips, eyes or genitalia,
- severe bloody diarrhoea (pseudomembranous colitis),
- jaundice (yellow colour of the skin and whites of the eyes), hepatitis (liver inflammation) - sometimes these effects on the liver can be delayed for up to 2 months after finishing treatment,
- serious skin reaction - a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis), A red rash caused by hypersensitivity to a drug or disease or other allergen (Erythema



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multiforme), severe rash with reddening, peeling and swelling of the skin that looks like a burn (toxic epidermal necrolysis).

- low potassium levels in the blood (hypokalaemia), which can cause muscle weakness, twitching or abnormal heart rhythm.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- minor stomach disturbances e.g. stomach upset, nausea (feeling sick) and diarrhoea.

*Less frequent side effects:*

- Blood abnormalities i.e Eosinophilia.
- very rare cases of blood and fluid abnormality may occur when XIXIA FLUCLOXACILLIN is used concomitantly with paracetamol.
- changes in liver function tests.
- urticaria (itchy skin eruption), purpura (brownish-red spots on the skin).
- arthralgia (joint pain) and myalgia (muscle pain).
- increased urine output (interstitial nephritis)
- fever that may occur more than 48 hours after treatment has started.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.



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### Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to **SAHPRA**: via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

### Aspen Pharmacare:

**E-mail:** [Drugsafety@aspenpharma.com](mailto:Drugsafety@aspenpharma.com)

**Tel:** 0800 118 088

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

## 5. How to store XIXIA-FLUCLOXACILLIN

Store all medicines out of reach of children.

Xixia-Flucloxacillin 250 – Keep tightly closed and store in a dry place, below 25 ° C.

Xixia-Flucloxacillin S – Keep tightly closed and store the dry powder below 25 ° C in a dry place.

The reconstituted suspension must be used within 7 days if stored below 25 ° C or 14 days if stored in a refrigerator (5 ° C).

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 XIXIA-FLUCLOXACILLIN contains**

The active substance is 250 mg of flucloxacillin per capsule.

The active substance is 125 mg of flucloxacillin per 5 ml of suspension.

The other ingredients are colour sunset yellow, disodium edetate, flavour blood orange dry, flavour menthol dry, flavour tutti frutti dry, glycamil, saccharin sodium, sodium citrate anhydrous, sodium benzoate sucrose.

### **What XIXIA-FLUCLOXACILLIN looks like and contents of the pack**

XIXIA-FLUCLOXACILLIN 250 is a black/red capsule.

XIXIA-FLUCLOXACILLIN S is a clear glass bottle containing a pinkish-white powder for reconstitution of an orange suspension.

Xixia-Flucloxacillin 250 – Amber glass bottles containing 20 or 100 capsules.

Xixia-Flucloxacillin S – Clear glass bottles containing powder for reconstitution of 100 ml suspension.

### **Holder of Certificate of Registration**

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead

2191

**Hotline:** 0800 122 912



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**This leaflet was last revised in**

19 April 2024

**Registration numbers**

XIXIA-FLUCLOXACILLIN 250 – 29/20.1.2/0550

XIXIA-FLUCLOXACILLIN S – 29/20.1.2/0551

**Access to the corresponding Professional Information**

**SAHPRA Repository of Professional Information and Patient Information**

**Leaflets:**

<https://www.sahpra.org.za/pi-pil-repository/>

**Aspen Pharmacare:**

**E-mail:** [Medinfo@aspenpharma.com](mailto:Medinfo@aspenpharma.com)

**Tel:** 0800 118 088

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