# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S4

**CLOXACILLIN FRESENIUS 250 mg** powder for solution for injection

**CLOXACILLIN FRESENIUS 500 mg** powder for solution for injection

**Cloxacillin sodium**

**Sugar free**

**Read all of this leaflet carefully before you are given CLOXACILLIN FRESENIUS**

- 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.

**What is in this leaflet**

1. What CLOXACILLIN FRESENIUS is and what it is used for

2. What you need to know before you are given CLOXACILLIN FRESENIUS

3. How CLOXACILLIN FRESENIUS is given to you

4. Possible side effects

5. How to store CLOXACILLIN FRESENIUS

6. Contents of the pack and other information

## 1. What CLOXACILLIN FRESENIUS is and what it is used for

CLOXACILLIN FRESENIUS belongs to the antibiotic group of medicines known as the penicillins.

CLOXACILLIN FRESENIUS is used to treat bacterial infections of the skin, bone, blood, heart valve, heart's inner lining and lungs.

## 2. What you need to know before you are given CLOXACILLIN FRESENIUS

**CLOXACILLIN FRESENIUS should not be administered to you:**

- If you are hypersensitive (allergic) to cloxacillin, penicillins or any other ingredients of CLOXACILLIN FRESENIUS (see **WHAT CLOXACILLIN FRESENIUS CONTAINS).**
- If you are hypersensitive (allergic) to cephalosporin antibiotics, such as cephalexin and cefuroxime, you may also be allergic to penicillin antibiotics.
- CLOXACILLIN FRESENIUS should not be used as an eye drop.
- CLOXACILLIN FRESENIUS should not be injected into the eye or spine.

**Warnings and precautions**

Tell your doctor or health care provider before being given the injection:

- if you have kidney problems.
- if you have syphilis.

Your doctor may need to monitor your kidney function and blood during treatment with CLOXACILLIN FRESENIUS.

**Take special care with CLOXACILLIN FRESENIUS:**

- In newborn babies with jaundice (yellow colouration of the skin and eye)
- If you are breastfeeding. CLOXACILLIN FRESENIUS is excreted in breast milk and may affect your baby.
- If you have a condition called porphyria. CLOXACILLIN FRESENIUS may cause porphyria attack.
- CLOXACILLIN FRESENIUS cannot be used together with the following antibiotics due to incompatibility: aminoglycosides, tetracyclines, erythromycin and polymyxin B.
- Your doctor may need to monitor your kidney function and blood during treatment with CLOXACILLIN FRESENIUS.
- Sensitivity reactions may include skin rashes, difficulty in breathing, swelling under the skin and itchy skin
- Your doctor may decide to perform a skin test for allergy, to determine if you are likely to develop an allergic reaction to penicillins

**Children and adolescents**

Take special care with CLOXACILLIN FRESENIUS in newborn babies with jaundice (yellow colouration of the skin and eye)

**Other medicines and CLOXACILLIN FRESENIUS**

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

The use of CLOXACILLIN FRESENIUS with other medicines you are taking on a regular basis, including complementary medicines (such as vitamin supplements) or traditional medicines, may cause undesirable interactions.

- Aminoglycoside antibiotics interact with CLOXACILLIN FRESENIUS causing both antibiotics to become inactive. Never use these antibiotics together.
- CLOXACILLIN FRESENIUS may also interact with other antibacterial medicines such as chloramphenicol and tetracyclines.
- blood thinning medication e.g. warfarin
- methotrexate – an immune suppressant medicine
- oral contraceptives – CLOXACILLIN FRESENIUS may decrease the effectiveness of birth control pills. Use a second method of birth control while taking CLOXACILLIN FRESENIUS to protect against pregnancy.
- Probenecid- medicine use for gout

**Not all the medicines that may interact with CLOXACILLIN FRESENIUS are listed above.**

**CLOXACILLIN FRESENIUS with food and drink and alcohol**

Not applicable.

**Pregnancy and breastfeeding and fertility**

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 you receive CLOXACILLIN FRESENIUS. Safety and efficacy during pregnancy and lactation have not been established. **Do not** use CLOXACILLIN FRESENIUS if you are pregnant, planning to become pregnant or breastfeeding your baby.
CLOXACILLIN FRESENIUS is excreted into breast milk and may affect your baby. Please consult your doctor.

**Driving and using machines:**

It is not always possible to predict to what extent CLOXACILLIN FRESENIUS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CLOXACILLIN FRESENIUS affects them.

**3. How CLOXACILLIN FRESENIUS is given to you.**

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

**You will not be expected to give yourself CLOXACILLIN FRESENIUS, it will be given to you by a person who is qualified to do so.** CLOXACILLIN FRESENIUS is given as an injection into a vein (intravenous), into a muscle (intramuscularly), into the heart (intrapleural) or into the joint (intra-articular). Your doctor will determine the correct dose of CLOXACILLIN FRESENIUS depending on your condition. To clear up your infection completely, CLOXACILLIN FRESENIUS will be administered for the full course of treatment, even if you feel better in a few days.
Your doctor will tell you how long your treatment with CLOXACILLIN FRESENIUS will last**.** If you have the impression that the effect of CLOXACILLIN FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

**If you receive more CLOXACILLIN FRESENIUS than you should:**

Since a health care provider will administer CLOXACILLIN FRESENIUS to you, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

**If you missed a dose of CLOXACILLIN FRESENIUS**

Since a health care provider will administer CLOXACILLIN FRESENIUS, it is unlikely that the dose will be missed.

**4. Possible side effects**

CLOXACILLIN FRESENIUS can have side effects.

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

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

- Skin: Itching, flushing, hives or swelling
- Eyes: Itching, tearing, redness or swelling of the skin around the eyes
- Nose and mouth: Sneezing, nasal congestion, swelling of the tongue
- Lungs and throat: Difficulty getting air in or out, chest tightness, throat swelling or itching
- Fits
- Unusual bleeding or bruising
- Decreased amount of urine
- Swelling of your face or lips
- Any signs of recurrent infections such as fever or sore throat

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

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

- Sore mouth and tongue
- Diarrhoea, nausea, vomiting
- Pain and swelling where CLOXACILLIN FRESENIUS was injected into your body
- Headaches
- Fever

- Unusual tiredness
- Joint pains
- Black hairy tongue
- Heartburn
- Flatulence

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. 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 CLOXACILLIN FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

**5. How to store CLOXACILLIN FRESENIUS**

Store at or below 25 $^{o}$C

Solutions for injection should preferably be freshly prepared but will retain their antibacterial potency for 24 hours at room temperature or for 4 days at 4 $^{o}$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).

**6. Contents of the pack and other information**

**What CLOXACILLIN FRESENIUS contains**

**Active ingredient:** Each vial contains cloxacillin sodium equivalent to 250 mg or 500 mg cloxacillin respectively.

**Inactive ingredient:** CLOXACILLIN FRESENIUS contains no other ingredients.

Sugar free

**What CLOXACILLIN FRESENIUS looks like and contents of the pack**

CLOXACILLIN FRESENIUS 250 mg:

A white crystalline hygroscopic powder in a clear glass vial.

CLOXACILLIN FRESENIUS 500 mg:

A white crystalline hygroscopic powder in a clear glass vial.

Packs of 10 and 50 vials

The container closure system consists of 15 mL clear glass vials type II (Ph Eur),

which after filling with the powder for injection is closed with a halobutyl stopper, and plastic flip-off cap.

**Holder of Certificate of Registration**

FRESENIUS KABI SOUTH AFRICA (PTY) LTD

Stand 7, Growthpoint Business Park

162 Tonetti Street

Halfway House, Extension 7

Midrand, Gauteng

1685

SOUTH AFRICA

Telephone number: (011) 545 0000

**This leaflet was last revised in**

16 September 2024

**Registration number(s)**

CLOXACILLIN FRESENIUS 250 mg: M/20.1.2/227

CLOXACILLIN FRESENIUS 500 mg: M/20.1.2/228

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|---|---|
| Botswana: | 250 mg: BOT08001156 S2 |
| Namibia: | 250 mg: NS2 90/20.1.2/0037 |
| | 500 mg: NS2 90/20.1.2/0038 |

**Access to the corresponding Professional Information**

The professional information will be printed and packaged with the product.