

PATIENT INFORMATION LEAFLET FOR SANDOZ FLUCLOXACILLIN 250

SCHEDULING STATUS: **S4**

SANDOZ FLUCLOXACILLIN (capsules)

Flucloxacillin

Sugar free

Read all of this leaflet carefully before you start taking SANDOZ FLUCLOXACILLIN

- 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.
- SANDOZ 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 SANDOZ FLUCLOXACILLIN is and what it is used for
2. What you need to know before you take SANDOZ FLUCLOXACILLIN
3. How to take SANDOZ FLUCLOXACILLIN
4. Possible side effects
5. How to store SANDOZ FLUCLOXACILLIN
6. Contents of the pack and other information

1. What SANDOZ FLUCLOXACILLIN is and what it is used for

Flucloxacillin is an antibiotic used to treat infections by killing the bacteria that can cause them.

It belongs to a group of antibiotics called "penicillins".

Applicant : Sandoz SA (Pty) Ltd
Proprietary name (dosage form) : SANDOZ FLUCLOXACILLIN (capsules)
Strength : Each capsule contains 250 mg flucloxacillin

V1.0 (11.09.2023)

SANDOZ FLUCLOXACILLIN capsules are used to treat:

- Infections caused by penicillinase producing *staphylococci*

2. What you need to know before you take SANDOZ FLUCLOXACILLIN

You should not take SANDOZ FLUCLOXACILLIN:

- If you are hypersensitive (allergic) to flucloxacillin or any of the other ingredients in SANDOZ FLUCLOXACILLIN (listed in section 6).
- If you previously had an allergic reaction to other antibiotics called cephalosporins or penicillins.
- If you have ever had liver problems (e.g. jaundice) after taking SANDOZ FLUCLOXACILLIN.

Warnings and precautions

Take special care with SANDOZ FLUCLOXACILLIN:

- Cross allergy between penicillin and cephalosporins may occur
- If you take SANDOZ FLUCLOXACILLIN by mouth, you may experience diarrhoea, feeling sick (nausea), heartburn and colic, pruritus ani, and disturbances of electrolyte balance
- If you have or develop diarrhoea.
- If you suffer from liver problems, as this medicine could cause them to worsen.
- If you are 50 years of age or older.
- If you have been taking this medicine for a long time, as regular tests of liver and kidney function are advised.
- If you suffer from kidney problems, as you may require a lower dose than normal (convulsions may occur very rarely in patients with kidney problems who take high doses).

- If you take SANDOZ 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 or will be taking paracetamol.
- If you see signs and symptoms of severe skin reaction please inform your doctor or pharmacist

Taking paracetamol at the same time as SANDOZ FLUCLOXACILLIN may result in a condition called high anion gap metabolic acidosis, which occurs when your body creates more acid and your blood becomes more acidic particularly in certain groups of patients at risk, e.g. patients with severe kidney problems, sepsis (a life threatening condition which occurs when the body reacts to an infection) or malnutrition, especially if the maximum daily doses of paracetamol are used. If you have taken paracetamol at the same time as SANDOZ FLUCLOXACILLIN, it is recommended that you are closely monitored to ensure that you do not develop high anion gap metabolic acidosis. High anion gap metabolic acidosis is a serious condition, which will require urgent medical treatment.

Skin contact with the contents of the capsules should be avoided, as SANDOZ FLUCLOXACILLIN may irritate the skin.

Children and adolescents

SANDOZ FLUCLOXACILLIN is not recommended for use in children.

Other medicines and SANDOZ FLUCLOXACILLIN

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

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

- Methotrexate (a chemotherapy medicine used to treat certain cancers)
- Warfarin (medicine to prevent blood clotting)

Applicant : Sandoz SA (Pty) Ltd
Proprietary name (dosage form) : SANDOZ FLUCLOXACILLIN (capsules)
Strength : Each capsule contains 250 mg flucloxacillin

V1.0 (11.09.2023)

- Probenecid or sulfinpyrazone (used to treat gout)
- Piperacillin (an antibiotic used to treat infections)
- Oral typhoid vaccine (antibiotics can make this less effective)
- Sugammadex (used with general anaesthetics)
- Other antibiotics (used to treat infections)
- Paracetamol
- Voriconazole (used to treat fungal infections)

Pregnancy, 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 health care provider for advice before taking this medicine.

The safety of SANDOZ FLUCLOXACILLIN during pregnancy has not been established. Do not use SANDOZ FLUCLOXACILLIN if you are pregnant.

Driving and using machines

Safety on your ability to drive or use machines after using SANDOZ FLUCLOXACILLIN is not yet known. If you experience sleepiness or dizziness, you should avoid driving and using machines.

SANDOZ FLUCLOXACILLIN contains Lactose

SANDOZ FLUCLOXACILLIN tablets contain an ingredient called lactose (milk sugar). If you have severe lactose intolerance, galactose intolerance, or glucose-galactose malabsorption, tell your doctor before taking SANDOZ FLUCLOXACILLIN capsules.

3. How to take SANDOZ FLUCLOXACILLIN

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

Applicant : Sandoz SA (Pty) Ltd
Proprietary name (dosage form) : SANDOZ FLUCLOXACILLIN (capsules)
Strength : Each capsule contains 250 mg flucloxacillin

V1.0 (11.09.2023)

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

The usual dose is 250 mg four times a day (every six hours).

Doses may be doubled in severe infections; up to 8 g daily in three or four divided doses may be given for endocarditis and osteomyelitis.

Take SANDOZ FLUCLOXACILLIN when your stomach is empty. This means one hour before meals.

Your doctor may need to reduce your dose if you have severe kidney problems.

If you take more SANDOZ FLUCLOXACILLIN than you should

In the event of overdose, consult your doctor or pharmacist. If neither are available, contact the nearest hospital or poison centre.

Symptoms of an overdose include feeling or being sick, vomiting, and diarrhoea. Symptoms should be treated.

If you forget to take SANDOZ FLUCLOXACILLIN

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose.

Do not take a double dose to make up for a missed dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you stop taking SANDOZ FLUCLOXACILLIN

Do not stop treatment early because some bacteria may survive and cause the infection to come back.

4. Possible side effects

SANDOZ FLUCLOXACILLIN can have side effects.

Not all side effects reported for SANDOZ FLUCLOXACILLIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SANDOZ FLUCLOXACILLIN, please consult your health care provider for advice.

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

- Hypersensitivity or severe allergic reaction including itchy rash, itching, sore mouth or eyes, swelling of the face, lips, throat or tongue or fever.
- Severe bloody diarrhoea (pseudomembranous colitis).
- Effects on the liver including jaundice (skin or the white of your eyes turning yellow) and hepatitis (liver inflammation) - sometimes these effects on the liver can be delayed for up to 2 months after finishing treatment.
- Erythema multiforme (a red rash caused by hypersensitivity to a medicine or disease or other allergen).
- Severe skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson Syndrome).
- Severe rash with reddening, peeling and swelling of the skin that looks like a burn (Toxic Epidermal Necrolysis).
- Serious skin reaction - A red, scaly rash with bumps under the skin and blisters (Acute Generalised Exanthematous Pustulosis).
- Risk of metabolic acidosis when flucloxacillin is used with paracetamol.

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

Other side effects that may be experienced while taking this medicine are:

Applicant : Sandoz SA (Pty) Ltd
Proprietary name (dosage form) : SANDOZ FLUCLOXACILLIN (capsules)
Strength : Each capsule contains 250 mg flucloxacillin

V1.0 (11.09.2023)

Frequent side effects:

- Feeling sick (nausea)
- Diarrhoea
- Minor gastrointestinal disturbances

Less-frequent side effects:

- Changes in numbers of different blood cells (causing unexplained bleeding, bruising or skin discolouration, and seen in blood tests)
- Rapid swelling (angioneurotic oedema)
- Allergic skin reactions that can cause swelling, itching and a rash (urticaria)
- Purpura (brownish-red spots on the skin)
- Arthralgia (pain in a joint) and myalgia (pain in the muscles)
- Interstitial nephritis (inflammation of the kidneys)
- Fever
- Very rare cases of increased acid production in the body (high anion gap metabolic acidosis), causing the blood to become more acidic (confirmed with a test), which may occur when SANDOZ FLUCLOXACILLIN is used together with paracetamol, generally in the presence of risk factors (see section 2).

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 “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of SANDOZ FLUCLOXACILLIN.

Applicant : Sandoz SA (Pty) Ltd
Proprietary name (dosage form) : SANDOZ FLUCLOXACILLIN (capsules)
Strength : Each capsule contains 250 mg flucloxacillin

V1.0 (11.09.2023)

Suspected side effects can also be reported directly to the HCR via
Patientsafety.sacg@novartis.com.

5. How to store SANDOZ FLUCLOXACILLIN

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep tightly closed and store in a dry place.

Protect from light.

6. Contents of the pack and other information

What SANDOZ FLUCLOXACILLIN contains

The active substance is flucloxacillin.

Each capsule contains flucloxacillin sodium equivalent to 250 mg flucloxacillin.

The other excipients are Brilliant Blue FCF (CI 42090), gelatine BP, iron oxide red (CI 77491), iron oxide yellow (CI 77492), magnesium stearate, microcrystalline cellulose, Povidone K29/32 (polyvinylpyrrolidone), silica colloidal anhydrous, sodium lauryl sulphate, sodium starch glycolate, talc, titanium dioxide (CI 77891).

What SANDOZ FLUCLOXACILLIN looks like and contents of the pack

SANDOZ FLUCLOXACILLIN are black and yellow opaque, size 2, hard gelatin capsules.

SANDOZ FLUCLOXACILLIN is packed in amber glass bottles or securitainers with 20, 40 or 100 capsules.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd¹

Magwa Crescent West

Applicant : Sandoz SA (Pty) Ltd
Proprietary name (dosage form) : SANDOZ FLUCLOXACILLIN (capsules)
Strength : Each capsule contains 250 mg flucloxacillin

V1.0 (11.09.2023)

Waterfall City

Jukskei View

Gauteng 2090

South Africa

This leaflet was last revised in

11 September 2023

Registration number

T/20.1.2/33

Access to the corresponding Professional Information

Not applicable.

¹Company Reg. No.: 1990/001979/07