

Approved Patient Information Leaflet for Medicines for Human Use:

XINOCLOC 250

SCHEDULING STATUS: S4

XINOCLOC 250 mg capsules

Flucloxacillin sodium

Sugar free

Read all of this leaflet carefully before you start taking XINOCLOC.

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

1. WHAT XINOCLOC is and what it is used for:

XINOCLOC contains the active substance called floxacillin. Flucloxacillin belongs to a class of antibiotics called “penicillinase-resistant penicillins” and is used to treat bacterial infections including:

Skin and soft tissue infections

Respiratory tract infections

Other infections

- Osteomyelitis (affecting the bone and bone marrow)
- Enteritis (affecting the intestinal tract, especially the small intestine)
- Endocarditis (inflammation of the lining of the heart and its valves),
- Kidney, bladder or urethra (the tube which carries urine from the bladder)
- Meningitis (a serious disease characterised by inflammation of the membranes around the brain or spinal cord)
- Septicaemia (blood poisoning)

2. What you need to know before you take XINOCLOC

Do not take XINOCLOC:

- If you are hypersensitive (allergic) to penicillins/flucloxacillin sodium or any of the other ingredients of XINOCLOC (listed in section 6).
- If you have had an allergic reaction to β -lactam antibiotics (e.g. penicillins, cephalosporins).
- If you have a previous history of flucloxacillin associated jaundice or hepatic dysfunction.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- If you have 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 are suffering from a condition called “syphilis”.
- if you are 50 years of age or older
- if you have other serious illness (apart from the infection this medicine is treating).
- 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 suffer from liver problems, as this medicine could cause them to worsen.
- 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 are on a sodium-restricted diet.
- if you are giving this medicine to a newborn child

There is a risk of blood and fluid abnormality (high anion gap metabolic acidosis) which occurs when there is an increase in plasma acidity, when flucloxacillin is used concomitantly with paracetamol, particularly in certain groups of patients at risk, e.g. patients with severe renal impairment, sepsis or malnutrition, especially if the maximum daily doses of paracetamol are used. High anion gap metabolic acidosis is a serious disease that must have urgent treatment.

Other medicines and XINOCLOC

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

Tell your health care provider if you are taking any of the following:

- probenecid or sulfinpyrazone (used in the treatment of gout)
- chloramphenicol
- erythromycin, clarithromycin or azithromycin (antibiotics - macrolides)
- linezolid
- doxycycline (an antibiotic)
- piperacillin (an antibiotic taken by injection)
- methotrexate (a chemotherapy medicine)
- oral typhoid vaccine (antibiotics can make this less effective)
- sugammadex (used in general anaesthetics)
- piperacillin (an antibiotic taken by injection)
- warfarin (medicine to prevent blood clotting)
- paracetamol

XINOCLOC with food and drink

Take XINOCLOC capsules half an hour to one (1) hour before meals.

Pregnancy and breastfeeding

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 XINOCLOC.

Tests

Regular monitoring kidney function should be performed whilst taking XINOCLOC for a long period of time. Tell your doctor that you are taking XINOCLOC if you are having urine tests or blood tests because it may affect the results.

Driving and using machines

XINOCLOC are not expected to affect your ability to drive or operate machinery.

3. How to take XINOCLOC

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

Always take XINOCLOC exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

For **oral use** only.

Take this medicine when your stomach is empty. This means an hour before food or 2 hours after food.

It is important that you take your medicine at the right times.

The dose will depend on the patient and will be decided by your doctor.

Adults

Take one (1) capsule four (4) times a day, your doctor may prescribe a different dose for severe infections.

- Joint infections (osteomyelitis) or heart infections (endocarditis) up to 8 g daily in divided doses, six to eight hourly.

Make sure you complete your prescribed course; do not stop taking XINOCLOC if you feel better.

If you still feel unwell after finishing the treatment, speak to your doctor.

Use in children and adolescents

XINOCLOC must not be given to children. Safety and efficacy has not been established.

If you take more XINOCLOC than you should

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

If you forget to take XINOCLOC

Do not take a double dose to make up for a forgotten tablet.

If you stop taking XINOCLOC

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

Do not stop taking XINOCLOC without first talking to your doctor.

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

4. POSSIBLE SIDE EFFECTS

XINOCLOC can have side effects.

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

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

- an allergic reaction, symptoms of which includes rash, itching, difficulty in breathing or swelling of the face, lips, throat or tongue
- severe bloody diarrhoea (pseudomembranous colitis)
- jaundice (yellow colour in 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
- 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).
- changes in numbers of blood cells (causing unexplained bleeding, bruising or skin discolouration).

These are very serious side effects. If you have them, you may have had a serious reaction to XINOCLOC. 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:

- difficulty breathing
- less urine than is normal for you
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems

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:

- Diarrhoea, nausea & vomiting

Less frequent side effects:

- Urticaria (itchy skin eruption)
- Purpura (brownish-red spots on the skin)
- Inflammation of the kidney

- Blood abnormalities i.e. neutropenia and thrombocytopenia, eosinophilia, haemolytic anaemia
- Anaphylactic Shock (severe allergic reaction)
- Angioneurotic Oedema (rapid swelling)
- Pseudomembranous colitis (type of inflammation of the colon)
- Changes in liver function tests
- Erythema multiforme (a red rash caused by hypersensitivity to a drug or disease or other allergen),
- Arthralgia (pain in a joint) and myalgia (pain in the muscles).
- Interstitial nephritis (Nephritis in which the interstitial connective tissue is chiefly affected)
- Very rare cases of blood and fluid abnormality (high anion gap metabolic acidosis) which occurs when there is an increase in plasma acidity, when flucloxacillin is used concomitantly with paracetamol, generally in the presence of risk factors (see section 2).

Some of these reactions can be delayed for up to two months after finishing the treatment.

Frequency not known:

- Serious skin reaction - A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis).
- Hypersensitivity reaction that affects your arteries that pump blood away from your heart, this may cause a heart attack or other heart problems.
- Hypersensitivity reaction that causes blisters in the skin (in the mouth, genitals or eyes).

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 or pharmacist. 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 XINOCLOC.

5. HOW TO STORE XINOCLOC

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original packaging.

There are no special storage instructions for XINOCLOC.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What XINOCLOC contains

The active substance is flucloxacillin sodium, 250 mg per capsule.

The other ingredients are:

- Magnesium stearate (E572), Colloidal anhydrous silica.
- Capsule Shell Body: red iron oxide (E172), yellow iron oxide (E172), titanium dioxide (E171), gelatin.
- Capsule shell cap: black iron oxide (E172), titanium dioxide (E171).

See Section 2 'Important information about some of the ingredients of XINOCLOC'.

What XINOCLOC looks like and contents of the pack

XINOCLOC is available polyethylene bags placed in white, round HDPE containers with white HDPE caps, including a silica gel bag, in pack sizes of 100 capsules.

XINOCLOC is available in Patient Ready Packs (PRP's) of Aluminium pouches, in pack sizes of 20 or 40 capsules.

XINOCLOC are hard gelatin capsules, elongated with grey / caramel body.

Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

JOHANNESBURG

2193

South Africa

Tel: 0860287835

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Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

<https://austell.co.za/product-info/>

Austell Pharmaceuticals (Pty) Ltd

Tel: +27 11 611 1400 or +27 860 287 835