PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

FLUCLOXACILLIN 250 mg OETHMAAN capsules

Flucloxacillin sodium

Sugar free

Read all of this leaflet carefully before you are given FLUCLOXACILLIN 250 mg OETHMAAN.

- 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.
- FLUCLOXACILLIN 250 mg OETHMAAN 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 FLUCLOXACILLIN 250 mg OETHMAAN is and what it is used for
2. What you need to know before you take FLUCLOXACILLIN 250 OETHMAAN
3. How to take FLUCLOXACILLIN 250 mg OETHMAAN
4. Possible side effects
5. How to store FLUCLOXACILLIN 250 mg OETHMAAN
6. Contents of the pack and other information

1. What FLUCLOXACILLIN 250 mg OETHMAAN is and what it is used for

FLUCLOXACILLIN 250 mg OETHMAAN contains the active substance flucloxacillin sodium which belongs to a group of antibiotics called penicillins and is used to treat infections caused by bacteria called penicillinase producing staphylococci.

2. What you need to know before you are given FLUCLOXACILLIN 250 mg OETHMAAN

Do not take FLUCLOXACILLIN 250 mg OETHMAAN:

- If you are hypersensitive (allergic) to flucloxacillin, penicillin, cephalosporins or any other antibiotics called beta-lactam antibiotics, or any of the other capsule ingredients (listed in section 6).
- If you have ever had liver problems (e.g. jaundice) after taking products containing penicillin or flucloxacillin (as contained in FLUCLOXACILLIN 250 mg OETHMAAN).

Warnings and precautions

Take special care with FLUCLOXACILLIN 250 mg OETHMAAN:

Check with your doctor or pharmacist before taking FLUCLOXACILLIN 250 mg OETHMAAN:

- if you have had an allergic reaction to β-lactam antibiotics (e.g. penicillins, cephalosporins)
- if you have, or have had liver problems before
- if you have a known history of allergies
- if you have any serious illness, other than this infection
- if you have porphyria
- if you have kidney problems
- If you have any heart problems or a history of heart disease.

Tell your doctor if you experience the following while taking FLUCLOXACILLIN 250 mg OETHMAAN:

- Serious skin reaction - A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). Contact your doctor immediately if you get any of these symptoms.
- 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.
- Severe allergic reactions which may include difficulty breathing, swelling of the face, lips, tongue, or throat, rash, itching, or hives. These reactions can sometimes lead to a heart problem called Kounis syndrome (also known as allergic angina), which can cause chest pain, shortness of breath, or a fast or irregular heartbeat.
- Any unusual blistering or skin eruptions. FLUCLOXACILLIN 250 mg OETHMAAN can cause a serious skin condition called Linear IgA bullous dermatosis (LABD).

Other medicines and FLUCLOXACILLIN 250 mg OETHMAAN

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

Tell your doctor if you are taking any other medicines before you start treatment with FLUCLOXACILLIN 250 mg OETHMAAN. It is especially important to talk to your doctor or pharmacist if you are taking any of the following:

- Probenecid or sulfinpyrazone (used to treat gout)
- Other medicines that may affect the liver.
- Oral contraceptives
- Any other antibiotics

- Voriconazole (used for fungal infections). The effectiveness of voriconazole may be reduced if used together with FLUCLOXACILLIN 250 mg OETHMAAN.
- Piperacillin (an antibiotic taken by injection)
- Oral typhoid vaccine (antibiotics can make this less effective)
- Methotrexate (a chemotherapy medicine)
- Sugammadex (used with general anaesthetics)
- Warfarin (medicine to prevent blood clotting)
- Paracetamol

FLUCLOXACILLIN 250 mg OETHMAAN with food and drink and alcohol

FLUCLOXACILLIN 250 mg OETHMAAN should be taken on an empty stomach, preferably one hour before meals or food.

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 FLUCLOXACILLIN 250 mg OETHMAAN.

Pregnancy

The safety of FLUCLOXACILLIN 250 mg OETHMAAN during pregnancy has not been established. Do not use FLUCLOXACILLIN 250 mg OETHMAAN if you are pregnant.

Breastfeeding

FLUCLOXACILLIN 250 mg OETHMAAN is found in human breast milk. If you take FLUCLOXACILLIN 250 mg OETHMAAN when you are breastfeeding, it may cause sensitivity to the medicine, diarrhoea, thrush or skin rash in your baby.

Driving and using machines

It is not always possible to predict to what extent FLUCLOXACILLIN 250 mg OETHMAAN 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 FLUCLOXACILLIN 250 mg OETHMAAN affects them.

FLUCLOXACILLIN 250 mg OETHMAAN is not known to affect ability to drive or use machinery.

FLUCLOXACILLIN 250 mg OETHMAAN contains sodium.

FLUCLOXACILLIN 250 mg OETHMAAN contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take FLUCLOXACILLIN 250 mg OETHMAAN

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

Always take FLUCLOXACILLIN 250 mg OETHMAAN exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. It is important not to take more or less medication than the amount prescribed.

It is important that you complete the full course of therapy. Do not stop the treatment early, do not miss doses, and take doses at evenly spaced intervals.

Usual adult dose:

One capsule (250 mg) every six hours, one hour before meals.

If you take more FLUCLOXACILLIN 250 mg OETHMAAN than you should

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

Treatment of an overdose with FLUCLOXACILLIN 250 mg OETHMAAN is symptomatic (relating to the symptoms) and supportive.

If you forget to take FLUCLOXACILLIN 250 mg OETHMAAN:

If you forget to take a dose, take the missed dose as soon as you notice it. However, if it is almost time for the next dose, skip the missed dose and continue with your regular dosage schedule. If you miss two or more doses contact your doctor.

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

If you stop taking FLUCLOXACILLIN 250 mg OETHMAAN

Do not stop taking FLUCLOXACILLIN 250 mg OETHMAAN because some bacteria may survive and cause the infection to come back.

Do not stop taking FLUCLOXACILLIN 250 mg OETHMAAN without asking your doctor first, even when you start to feel better. It is important that you keep taking FLUCLOXACILLIN 250 mg OETHMAAN or the duration your doctor has prescribed your medicine for.

4. POSSIBLE SIDE EFFECTS:

FLUCLOXACILLIN 250 OETHMAAN can have side effects.

Not all side effects reported for FLUCLOXACILLIN 250 mg OETHMAAN are included in this leaflet. Should your general health worsen while taking FLUCLOXACILLIN 250 mg OETHMAAN, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking FLUCLOXACILLIN 250 mg OETHMAAN 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 FLUCLOXACILLIN 250 mg OETHMAAN. 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:

- less urine than is normal for you (interstitial nephritis)
- 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:

The following side effects may be experienced while using **FLUCLOXACILLIN 250 mg OETHMAAN:**

Frequent:

- Headache,
- Diarrhoea, nausea, vomiting,

- Thrush, yeast infection of the vagina associated with itching, burning and curd-like white discharge.

Less frequent:

- Sudden, life-threatening allergic reaction (anaphylaxis); Allergic reactions presenting as an itchy, red skin rash with swelling and fever, eosinophilia (increase in white blood cells), joint pains and exfoliative dermatitis (flaking, inflammatory skin condition). Should an allergic or anaphylactic reaction occur, **FLUCLOXACILLIN 250 mg OETHMAAN** should be discontinued and your doctor consulted for the appropriate treatment.
- Rash, hives, a rash of purple spots,
- Joint pain, muscle aches and pain,
- Fever.

The following side effects have been reported but their frequencies are unknown:

- Reduction in white blood cells
- Heartburn, colic, pruritus ani (itching of the anal region), inflammation of the colon caused by *Clostridium difficile*
- Liver toxicity, hepatitis (inflammation of the liver) and cholestatic jaundice (causing yellowish discolouration of the skin, whites of eyes and mucous membranes)
- Erythema multiforme (skin rash with circular, red patches), Stevens-Johnson syndrome (severe skin rash with flushing, fever, blisters or ulcers), toxic epidermal necrolysis (severe rash with reddening, peeling and swelling of the skin that resembles burns)
- Disturbances of electrolyte balance
- Acute attacks of porphyria

- Seizures
- 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).
- Serious skin reaction - A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). Contact your doctor immediately if you get any of these symptoms.
- Severe allergic reactions which may include difficulty breathing, swelling of the face, lips, tongue, or throat, rash, itching, or hives. These reactions can sometimes lead to a heart problem called Kounis syndrome, which can cause chest pain, shortness of breath, or a fast or irregular heartbeat. If you experience any of these symptoms, stop taking FLUCLOXACILLIN 250 mg OETHMAAN and seek medical attention immediately.
- Severe skin reactions, including Linear IgA bullous dermatosis (LABD). Symptoms can include itchy or painful blisters, often in a line or cluster, and areas of raw or denuded skin. If you experience any of these symptoms, stop taking FLUCLOXACILLIN 250 mg OETHMAAN and seek medical attention immediately.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 FLUCLOXACILLIN 250 mg OETHMAAN.

5. How to store FLUCLOXACILLIN 250 mg OETHMAAN

Store in a dry place at or below 25 °C.

Do not remove the blister from the carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

Do not store in bathrooms.

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

Return all unused medicine to your pharmacy. Do not dispose of unused medicine in drains or sewerage systems e.g. toilets.

6. Contents of the pack and other information

What FLUCLOXACILLIN 250 mg OETHMAAN contains

The active substance is flucloxacillin sodium equivalent to 250 mg flucloxacillin.

The other ingredients are:

- colloidal anhydrous silica, magnesium stearate.
- capsule shell body: iron oxide red (CI no. 77491), iron oxide yellow (CI no. 77492), titanium dioxide (CI no. 77891), gelatine.
- capsule shell cap: iron oxide black (CI no. 77499), titanium dioxide (CI no. 77891), gelatine.

What FLUCLOXACILLIN 250 mg OETHMAAN looks like and contents of the pack

Size 2, caramel and black coloured hard gelatin capsule filled with white to almost white granular powder.

FLUCLOXACILLIN 250 mg OETHMAAN are packed in:

20, 28 and 40 capsules packed in opaque white PVC/silver aluminium foil blister strips packed in cardboard cartons or 20, 40 and 100’s capsules packed in aluminium laminated PRP pouch and 100’s packed in securitainers.

Holder of Certificate of Registration

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2195

This leaflet was last revised in

To be advised

Registration number

44/20.1.2/0816

Access to the corresponding Professional Information

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