

**Approved Patient Information Leaflet for Medicines for Human Use:**

**FLUCLOXACILLIN 250 mg AUSTELL**

**SCHEDULING STATUS:** S4

**FLUCLOXACILLIN 250 mg AUSTELL capsules**

**Flucloxacillin sodium**

**Sugar free**

**Read all of this leaflet carefully before you start taking FLUCLOXACILLIN 250 mg AUSTELL.**

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

**1. WHAT FLUCLOXACILLIN 250 mg AUSTELL is and what it is used for:**

FLUCLOXACILLIN 250 mg AUSTELL contains the active substance called flucloxacillin. 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 FLUCLOXACILLIN 250 mg**

**AUSTELL**

**Do not take FLUCLOXACILLIN 250 mg AUSTELL:**

- If you are hypersensitive (allergic) to penicillins/flucloxacillin sodium or any of the other ingredients of FLUCLOXACILLIN 250 mg AUSTELL (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.

**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 FLUCLOXACILLIN 250 mg AUSTELL**

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

### **FLUCLOXACILLIN 250 mg AUSTELL with food and drink**

Take FLUCLOXACILLIN 250 mg AUSTELL 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 FLUCLOXACILLIN 250 mg AUSTELL.

### **Tests**

Regular monitoring kidney function should be performed whilst taking FLUCLOXACILLIN 250 mg AUSTELL for a long period of time. Tell your doctor that you are taking FLUCLOXACILLIN 250 mg AUSTELL if you are having urine tests or blood tests because it may affect the results.

### **Driving and using machines**

FLUCLOXACILLIN 250 mg AUSTELL are not expected to affect your ability to drive or operate machinery.

### **3. How to take FLUCLOXACILLIN 250 mg AUSTELL**

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

Always take FLUCLOXACILLIN 250 mg AUSTELL 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

FLUCLOXACILLIN 250 mg AUSTELL if you feel better.

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

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

FLUCLOXACILLIN 250 mg AUSTELL must not be given to children. Safety and efficacy has not been established.

**If you take more FLUCLOXACILLIN 250 mg AUSTELL than you should**

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

**If you forget to take FLUCLOXACILLIN 250 mg AUSTELL**

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

**If you stop taking FLUCLOXACILLIN 250 mg AUSTELL**

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

FLUCLOXACILLIN 250 mg AUSTELL can have side effects.

Not all side effects reported for FLUCLOXACILLIN 250 mg AUSTELL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FLUCLOXACILLIN 250 mg AUSTELL, please consult your health care provider for advice.

If any of the following happens, stop taking FLUCLOXACILLIN 250 mg AUSTELL 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 AUSTELL. 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).

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 FLUCLOXACILLIN 250 mg AUSTELL.

## **5. HOW TO STORE FLUCLOXACILLIN 250 mg AUSTELL**

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 FLUCLOXACILLIN 250 mg AUSTELL.

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 FLUCLOXACILLIN 250 mg AUSTELL 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 FLUCLOXACILLIN 250 mg AUSTELL'.

### **What FLUCLOXACILLIN 250 mg AUSTELL looks like and contents of the pack**

Austell Pharmaceuticals (Pty) Ltd, 550223.222, FLUCLOXACILLIN 250 AUSTELL, Capsules

FLUCLOXACILLIN 250 mg AUSTELL 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.

FLUCLOXACILLIN 250 mg AUSTELL is available in Patient Ready Packs (PRP's) of Aluminium pouches, in pack sizes of 20 or 40 capsules.

FLUCLOXACILLIN 250 mg AUSTELL 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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