SCHEDULING STATUS: S4

SEPTAPEN 250 capsules

Flucloxacillin sodium

Sugar free

Read all of this leaflet carefully before you start taking SEPTAPEN 250.

• 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.

• **SEPTAPEN 250** 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 **SEPTAPEN 250** is and what it is used for

2. What you need to know before you take **SEPTAPEN 250**

3. How to take **SEPTAPEN 250**

4. Possible side effects

5. How to store **SEPTAPEN 250**

6. Contents of the pack and other information

1. WHAT SEPTAPEN 250 is and what it is used for:

SEPTAPEN 250 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)
    - Otitis Media (infection of the ear)
    - Wounds and burn wounds.

2. What you need to know before you take SEPTAPEN 250

Do not take SEPTAPEN 250:

- If you are hypersensitive (allergic) to penicillins/flucloxacillin sodium or any of the other ingredients of **SEPTAPEN 250** (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 taking or will be taking paracetamol
- if you are taking this medicine for a long time as regular tests of liver and kidney function are advised
- if you suffer from liver problems, as this medicine could cause them to worsen.

Tests

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

Use in children and adolescents

SEPTAPEN 250 must not be given to children. Safety and efficacy has not been established.

Other medicines and SEPTAPEN 250

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)
- piperacillin (an antibiotic taken by injection)
- methotrexate (a chemotherapy medicine)
- oral typhoid vaccine (antibiotics can make this less effective)
- sugammadex (used in general anaesthetics)
- warfarin (medicine to prevent blood clotting)
- paracetamol
- Voriconazole (used to treat fungal infection- flucloxacillin can reduce levels of this medicine in your body)

SEPTAPEN 250 with food and drink

Take **SEPTAPEN 250** 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 **SEPTAPEN 250**.

Driving and using machines

SEPTAPEN 250 are not expected to affect your ability to drive or operate machinery.

It is not always possible to predict to what extent **SEPTAPEN 250** 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 **SEPTAPEN 250** affects them.

3. How to take SEPTAPEN 250

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

Always take **SEPTAPEN 250** 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.

Kidney problems:

The dose may need to be reduced; your doctor will prescribe a suitable dose for you.

If you take more SEPTAPEN 250 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 SEPTAPEN 250

If you miss a dose, take it as soon as you remember and carry on as before.
If it is almost time for your next dose, skip the missed dose and continue as usual.
Do not take a double dose to make up for a forgotten dose.

If you stop taking SEPTAPEN 250

Do not stop taking **SEPTAPEN 250** because some bacteria may survive and cause the infection to come back. Do not stop taking **SEPTAPEN 250** without first talking to your doctor.

4. POSSIBLE SIDE EFFECTS

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

If any of the following happens, stop taking **SEPTAPEN 250** 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 **SEPTAPEN 250**. 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:

- Diarrhoea, nausea & vomiting

Less frequent:

- 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 **SEPTAPEN 250**.

5. HOW TO STORE SEPTAPEN 250

Store all medicines out of reach of children.

Store at or below 25 °C, in dry place

Store in the original packaging.

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

Do not store in the bathroom.

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 SEPTAPEN 250 contains

The active substance is flucloxacillin sodium.

The other ingredients are:

Magnesium stearate.

Size 2 black/red hard gelatine capsule components:

Black oxide, erythrosine, gelatine, red oxide, titanium dioxide

What SEPTAPEN 250 looks like and contents of the pack

SEPTAPEN 250 capsules are black/red size "2" hard gelatine capsules.

SEPTAPEN 250 is available in:

Amber glass bottles containing 20 or 100 capsules.

20's, 100's and 40's printed Alu/LDPE patient ready packs.

PP/HDPE securitainers containing 20 or 100 capsules.

Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

Innovata Pharmaceuticals (Pty) Ltd

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2091

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Access to the corresponding Professional information.

Follow the link for the corresponding Professional Information for **SEPTAPEN**:

pi-pil-repository.innovata.co.za,

alternatively please scan the QR code below:

