

Floxapen® 250mg and 500mg capsules (flucloxacillin)

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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1. What Floxapen capsules are and what they are 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”.

Floxapen capsules are used to treat:

- chest infections
- throat or nose infections
- ear infections
- skin and soft tissue infections
- heart infections
- bones and joints infections
- meningitis
- digestive system infections
- blood infections
- kidney, bladder or urethra (the tube which carries urine from the bladder) infections.

Floxapen capsules can also be used to prevent infections during major surgery, particularly heart or orthopaedic surgery.

2. Before you take

Do not take Floxapen capsules and tell your doctor if you:

- are **allergic** (hypersensitive) to flucloxacillin, penicillin, any other antibiotic or any of the other ingredients (see section 6)
- have ever had **liver problems after taking flucloxacillin.**

Check with your doctor or pharmacist before taking Floxapen capsules if you:

- have **liver** or **kidney** problems
- have any **serious illness**, other than this infection
- are on a **low sodium diet**

- are **50 years old or over**.
 - are taking or will be taking paracetamol.
- 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.

Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- probenecid (to treat gout)
- other antibiotics (used to treat infections)

Pregnancy and breast feeding

If you are pregnant, planning to become pregnant or are breast feeding ask your doctor or pharmacist for advice before taking this medicine.

Tests

Regular monitoring of liver and kidney function should be performed whilst taking Floxapen capsules.

Tell your doctor that you are taking Floxapen if you are having urine tests or blood tests because Floxapen may affect the results.

Sodium content

Each 250mg capsule contains 13mg of sodium and each 500mg capsule contain 25mg of sodium.

3. How to take

Always take Floxapen capsules exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Swallow the capsules **whole** with water, **do not chew** them, **half to one hour before meals**. Never take more than the recommended dose each day.

Doses:

- Adults - one 250mg capsule four times a day, your doctor may prescribe a different dose for severe infections.
- Joint infections (osteomyelitis) or heart infections (endocarditis) - up to 8g daily in divided doses, six to eight hourly.
- To prevent infection due to surgery - 1 to 2g by injection into a vein, at the same time as the anaesthetic, followed by 500mg six hourly either by mouth or injection into a vein or muscle for up to 72 hours.
- Children aged 2-10 years - half the adult dose.
- Children under 2 years - quarter the adult dose.
- Premature or babies less than 4 weeks old – Not recommended.
- Severe kidney disease - your doctor may reduce your dose.

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

If you take more than you should

If you (or someone else) swallow a lot of capsules at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include feeling or being sick and diarrhoea.

If you forget to take the capsules

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and carry on as before, try to wait about four hours before taking the next dose.

If you stop taking the capsules

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

4. Possible side effects

Like all medicines, Floxapen capsules can cause side effects, although not everybody gets them. Please tell your doctor or pharmacist if you notice any of the following effects or any effects not listed.

Stop taking Floxapen capsules and contact your doctor at once if you experience any of the following:

- hypersensitivity or severe allergic reaction including itchy rash, itching, sore mouth or eyes, swelling of the face, lips, throat or tongue or breathing problems.
- severe bloody diarrhoea (pseudomembranous colitis).

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Common (occurs in less than 1 in 10 users): minor stomach disturbances e.g. stomach upset or diarrhoea.

Very rare (occurs in less than 1 in 10,000 users): inflammation of the kidney or liver, jaundice (skin or the white of your eyes turning yellow), changes in numbers of blood cells (causing unexplained bleeding, bruising or skin discolouration), anaemia, skin rash with circular, red patches (Erythema multiforme), severe skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome) or a severe rash with reddening, peeling and swelling of the skin that resembles burns (toxic epidermal necrolysis). Joint or muscle pain or fever, may develop after 2 days or more from the start of treatment with Floxapen capsules. 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.

Not known (frequency cannot be estimated from the available data)

Serious skin reactions - A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). Contact a doctor immediately if you get any of these symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store

Keep out of the sight and reach of children.

Store in a dry place in the original package.

Do not use Floxapen capsules after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.


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. Further information

What Floxapen capsules contain

- The active substance (the ingredient that makes the capsules work) is flucloxacillin. Each capsule contains either 250mg or 500mg of the active ingredient.
- The capsule also contains: magnesium stearate.
- The capsule shell contains: gelatin, titanium dioxide (E171), black iron oxide (E172), yellow iron oxide (E172), red iron oxide (E172).
- The printing ink contains: shellac (E904), propylene glycol (E1520), sodium hydroxide (E524), povidone, titanium dioxide (E171)

What Floxapen capsules look like and contents of the pack

Floxapen are caramel hard gelatin capsules (body) fitted with black caps.  is printed on the black cap. The 250mg capsule has '250' on the body and the 500mg capsule has '500' on the body.

Pack sizes of 28

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