

PACKAGE LEAFLET: INFORMATION FOR THE USER
Flucillin - Flucloxacillin 250 mg and 500 mg 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.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Flucillin is and what it is used for
2. Before you take Flucillin
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1. WHAT FLUCILLIN IS AND WHAT IT IS USED FOR

Flucillin is a member of a group of antibiotics called “penicillins” and is used for the treatment of various infections caused by bacteria.

2. BEFORE YOU TAKE FLUCILLIN

Do NOT take Flucillin if you:

- are allergic (hypersensitive) to similar ‘beta-lactam’ antibiotics (including penicillin, cephalosporin), flucloxacillin or any of the ingredients in the product (*see Section 6 and end of Section 2*)
- have ever had liver problems after taking flucloxacillin e.g. jaundice – yellowing of the skin or eyes.

Take special care with Flucillin

Consult your doctor if you:

- have had a previous sensitivity to any beta-lactam penicillins or cephalosporins – if any reactions occur you may need immediate help (*see Section 4*)
- have liver or kidney problems
- have any serious illness, other than the infection being treated with these capsules
- are over 50

The use of flucloxacillin, especially in high doses, may reduce the potassium levels in the blood (hypokalaemia). Your doctor may measure your potassium levels regularly during the therapy with higher doses of flucloxacillin.

Long term treatment

Regular monitoring of liver and kidney function should be performed during prolonged treatment with Flucillin.

Tests

This medicine may cause a false result of liver function tests – tell the doctor that you are taking Flucillin if you are having blood or urine tests.

Taking other medicines

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

- probenecid (to treat gout)
- oral contraceptives
- chloramphenicol (used to treat eye infections) or tetracycline (used to treat acne)
- voriconazole (used against fungal infections).

If you 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.

Pregnancy and breast-feeding

Flucillin should not be used during pregnancy unless your doctor considers it essential. Flucillin passes into breast milk, which may be harmful for the infant. If you are pregnant, planning to become pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking Flucillin or any other medicine.

Driving and using machines

Do not drive or operate machinery unless you know that Flucillin has no effect on your physical ability and mental alertness.

Important information about some of the ingredients of Flucillin

Flucillin contains:

- Sodium – Each 250 mg capsule contains 12.75 mg of sodium. Each 500 mg capsule contains 25.5 mg of sodium, which must be taken into consideration by patients on a controlled sodium diet.

3. HOW TO TAKE FLUCILLIN

Always take this medicine exactly as the doctor has told you; you should check with him/her if you are not sure. The dose will depend on the nature and severity of your infection.

Take your flucloxacillin capsule at least 1 hour before or 2 hours after meals.

To reduce the risk of pain in your oesophagus (the tube that connects your mouth with your stomach) swallow capsule with a full glass of water (250 ml) and do not lie down immediately after taking your capsule.

Dose

- **Adults (and children over 10 years of age):** usual daily dose: 250 - 500 mg three times a day which may be increased as necessary.
- **Usual childrens dosage :**
Children aged 2 - 10 years: the usual daily dose is half the adult dose - (125 mg - 250 mg three times a day) which may be increased as necessary by the doctor.

- **Children under 2 years:** the usual daily dose is a quarter of the adult dose (62.5 - 125 mg three times a day) but may be increased by the doctor; an oral suspension is available for very young children.
- **Joint infections (osteomyelitis) or heart infections (endocarditis):** up to 8 g daily in divided doses six to eight - hourly.
- **To prevent infection due to surgery:** 1 - 2 g by injection into a vein, at the same time as the anaesthetic, followed by 500 mg six hourly either by mouth or injection into a vein or muscle at six hourly intervals for up to 72 hours.
- **Patients with severe kidney problems:** your dose will usually be reduced.

If you take more Flucillin than you should

If you have taken more medicine than you should, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this leaflet and/or the bottle with you if you can. The following symptoms of overdose may occur: nausea, vomiting and diarrhoea.

If you forget to take Flucillin

If you have missed a dose, take one as soon as you remember, unless it is nearly time for your next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Flucillin

It is important that you finish the full course of treatment, even if you begin to feel better after a few days, otherwise your infection could return.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Flucillin may cause side effects, although not everybody gets them.

STOP taking this medicine and **seek medical help immediately** if you have any of the following:

- an allergic reaction (hypersensitivity), including difficulty breathing or swallowing, swelling of the face, lips, tongue or throat, severe itching of the skin with a rash, severe bloody diarrhoea (pseudomembranous colitis).

Other side effects:

Common (affecting less than 1 in 10 people but more than 1 in 100 people)

- minor stomach complaints such as nausea and diarrhoea.

Uncommon (affecting less than 1 in 100 people but more than 1 in 1,000 people)

- skin rashes: red or raised bumps (hives), bleeding under the skin (bruising).

Very rare (affecting less than 1 in 10,000 people)

- anaphylactic shock (severe hypersensitivity – see above)
- rapid swelling of the skin, tissues, internal organs or brain
- yellowing of the skin and whites of eyes, dark coloured urine (liver problems) symptoms may be delayed up to 2 months after treatment

- kidney inflammation, decreased urine output or blood in the urine; this is reversible when treatment stops
- muscle and joint pain - sometimes this develops more than 48 hours after treatment starts
- blood abnormalities including haemolytic anaemia (due to red blood cell destruction) – may lead to tiredness, breathlessness, lightheadedness, a rapid weak pulse or palpitations, headaches or yellowing of the skin and eyes; these are reversible when treatment is stopped.
- severe skin reactions (erythema multiforme - symptoms are: fever, general feeling of being unwell, itching of skin, or joint aches; Stevens-Johnson syndrome - symptoms are: fever, sore throat and fatigue, ulcers and lesions in the mouth and genital/anal regions; toxic epidermal necrolysis - symptoms are: fever, chest infection, rash, saggy skin peeling off in great swaths).
- fever which sometimes develops more than 48 hours after treatment starts
- epileptic fits, particularly in patients with kidney failure
- inflammation of the colon (pseudomembranous colitis) - symptoms are: severe diarrhoea with blood or mucus, fever, abdominal pain
- bruising, nose bleeds or bleeding gums (thrombocytopenia)
- breathless, wheezing, diarrhoea and fever (eosinophilia)
- mouth ulcers, sore throat, burning sensation when passing water (neutropenia).
- 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).

Other side effects (frequency not known)

- 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.
- Low potassium levels in the blood (hypokalaemia), which can cause muscle weakness, twitching or abnormal heart rhythm.
- Pain in oesophagus (the tube that connects mouth with stomach) and other related symptoms, such as difficulties in swallowing, heartburn, throat irritation or chest pain.

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 HPRC Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FLUCILLIN

Keep out of the sight and reach of children. Do not use Flucillin after the expiry date shown on the label. Do not store this product above 25°C. 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 Flucillin contains

The **active substance** is flucloxacillin; each capsule contains either 250 mg or 500 mg flucloxacillin (as flucloxacillin sodium).

The **other ingredients** are:

powder: magnesium stearate, colloidal anhydrous silica,

capsule shell: black iron oxide (E172), red iron oxide (E172), yellow iron oxide (E172), titanium dioxide (E171), gelatin,

printing ink: shellac glaze, black iron oxide (E172), propylene glycol (E1520) (*see end of Section 2 for information on sodium*).

What Flucillin looks like and contents of the pack

These capsules are hard with caramel coloured bodies and grey caps, printed 'FXN 250' or 'FXN 500' in black and contain a white granular powder. They are supplied in plastic containers containing 20, 40, 100 or 500 capsules, with or without a Jayfilla. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary.

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