

Package Leaflet: Information for the user

Fluclon 250 mg Hard Capsules

Fluclon 500 mg Hard Capsules

Active substance: Flucloxacillin (as sodium)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you..

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Fluclon Capsules are and what they are used for
2. What you need to know before you take Fluclon Capsules
3. How to take Fluclon Capsules
4. Possible side effects
5. How to store Fluclon Capsules
6. Contents of the pack and other further information

1. What Fluclon Capsules are and what they are used for

‘Fluclon’ is an antibiotic medicine and contains the active ingredient flucloxacillin. It is a penicillin antibiotic used to treat infections in different parts of your body caused by bacteria. It belongs to a group of medicines called penicillinase-resistant antibiotics.

2. What you need to know before you take Fluclon Capsules

DO NOT TAKE Fluclon Capsules if you:

- have ever had an allergic reaction to flucloxacillin, any other penicillin antibiotics or cephalosporins (see possible side effects, section 4), or to any of the other ingredients of this medicine (listed in section 6)
- have had liver problems in the past as a result of taking flucloxacillin.

WARNINGS AND PRECAUTIONS

Talk to your doctor or pharmacist before taking Fluclon capsules

Take special care with Fluclon Capsules if you:

- suffer from serious kidney problems, as you may require a lower dose than normal
- suffer from liver problems, as this medicine could cause them to worsen
- are taking the contraceptive pill, as you will need to take extra precautions
- are on a low sodium diet (see section ‘Important information about some of the ingredients of Fluclon’).

Prolonged use of an antibiotic may result in infections due to bacteria resistant to the antibiotic.

OTHER MEDICINES AND FLUCLON CAPSULES:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:

- Other antibiotics (to treat infections)
- Probenecid (to treat gout)
- Oral contraceptives (“the pill”)
- Warfarin (used to prevent blood clots)

Some medicines may affect the way others work. Always tell your doctor about all the medicines you are taking. This means medicines you have bought yourself as well as the medicines on prescription from a doctor.

PREGNANCY, BREAST-FEEDING AND FERTILITY:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine

DRIVING AND USING MACHINES

Fluclon capsules are unlikely to affect your ability to drive or use machines. However, make sure you know how you react to Fluclon capsules before driving a vehicle or operating machinery. If in doubt, talk to your doctor.

FLUCLON CONTAINS SODIUM:

This medicine contains up to 12.5 mg sodium per capsule in ‘Fluclon 250mg Capsules’, and up to 25 mg sodium per capsule in ‘Fluclon 500mg Capsules’. To be taken into consideration by patients on a controlled sodium diet.

3. How to take Fluclon Capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Their directions may differ from the information contained in this leaflet. The pharmacist’s label should tell you how much to take and how often. Check with your doctor or pharmacist if you are not sure.

Adults and children over 10 years of age: The usual dose is 250 to 500 mg three times daily.

Children under 10 years of age: Not recommended.

Osteomyelitis (bone infection) and endocarditis (inflammation of the lining of the heart): Up to 8 g daily in divided doses, taken every 6 to 8 hours.

Abnormal kidney function: In patients with kidney impairment a dosage reduction is not usually required. A reduction in dose or an extension of the dose interval may be necessary however if you have severe kidney failure.

The doses should be spaced as evenly as possible throughout the day. It is not normally necessary to take a dose in the middle of the night, unless instructed to do so by your doctor.

When you take your medicine:

Take your medicine on an empty stomach, at least thirty minutes to one hour before meals/food. It is important that you take your medicine at the right times. Swallow the capsules with a drink of water.

How long to take your medicine for:

Keep taking your medicine until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, your infection may return or get worse.

If you take more Fluclozole than you should:

If you (or somebody else) take too much of your medicine, talk to your doctor or pharmacist immediately.

If you forget to take Fluclozole:

If you forget to take a dose, take it as soon as you remember, then carry on as before. Do not take a double dose to make up for the dose you have missed.

4. Possible side effects

Like all medicines, Fluclozole Capsules can cause side effects, although not everyone gets them. The evaluation of the side effects is based on the following frequencies:

Very common:	In more than 1 in 10 patients treated
Common:	In less than 1 in 10, but more than 1 in 100 patients treated
Uncommon:	In less than 1 in 100, but more than 1 in 1,000 patients treated
Rare:	In less than 1 in 1,000, but more than 1 in 10,000 patients treated
Very rare:	In less than 1 in 10,000 patients treated, including single reports
Not known:	Frequency cannot be estimated from the available data

Stop taking Fluclozole Capsules immediately and see your doctor if you experience any of the following symptoms:

- 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)

Other possible side effects:

Common:

- Minor stomach disturbances e.g. stomach upset or diarrhoea.

Uncommon:

- Rash, hives (urticaria), red or purple patches on the skin or bleeding under the skin.

Very rare:

- 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)
- Skin rash with circular red patches (Erythema multiforme)
- Severe skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome)
- 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 Fluclofen Capsules.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fluclofen Capsules

Do not store above 25°C. Keep the container tightly closed.

Keep out of the sight and reach of children.

Do not use Fluclofen capsules after the expiry date (EXP) stated on the container. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Flucloxacillin capsules contain:

The active substance is **flucloxacillin** as flucloxacillin sodium. Each capsule contains 250 mg or 500 mg flucloxacillin.

The other ingredients are magnesium stearate. The capsule shells contain gelatin, titanium dioxide (E171), patent blue V (E131) and erythrosine (E127).

What Flucloxacillin capsules look like and contents of the pack:

Flucloxacillin capsules are hard, opaque, blue capsules printed with a twin triangle logo and 'FXN 250' (250mg) or 'FXN 500' (500mg).

Fluclofen 250 mg capsules are available in packs containing 10, 50, 100, 250, 500 and 1000 capsules. Fluclofen 500 mg capsules are available in packs containing 50, 100, 250, 500 and 1000 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Clonmel Healthcare Ltd.,
Waterford Road,
Clonmel,
Co. Tipperary

This leaflet was last approved in September 2014