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**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Flucloxacillin 500 mg Capsules**  
Flucloxacillin as Flucloxacillin 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.
- 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 have any further questions, please ask your doctor or pharmacist
- 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**

- What Flucloxacillin Capsule is and what it is used for
- What you need to know before you take Flucloxacillin Capsules
- How to take Flucloxacillin Capsules
- Possible side effects
- How to store Flucloxacillin Capsules
- Contents of the pack and other information

**1. WHAT FLUCLOXACILLIN CAPSULES ARE AND WHAT THEY ARE USED FOR**

Flucloxacillin Capsules contain the active ingredient flucloxacillin (as flucloxacillin sodium). Flucloxacillin is one of a group of antibiotics called penicillinase-resistant penicillins. It is used to kill bacteria which cause infections in your body.

Flucloxacillin Capsules are used to treat a wide range of bacterial infections which may include those affecting the chest and lungs, the pharynx, tonsils, sinuses and ears. They are also used to treat skin and soft tissue infections such as boils, carbuncles, skin ulcers, abscesses, eczema, acne, infected wounds and burns, and also for skin-graft protection. They are also used to treat infections affecting the intestines, heart (i.e. endocarditis), membranes of the brain (i.e. meningitis), blood, bones, joints and urinary tract (kidney, bladder, urethra).

Flucloxacillin can also be used to prevent an infection occurring during major surgery, particularly in heart or orthopaedic surgery.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLUCLOXACILLIN CAPSULES**

**Do not take Flucloxacillin capsules:**

- If you know you are allergic to flucloxacillin or to any of the other ingredients (listed in section 6)
- If you have ever had an allergic reaction (e.g. rash, itching, shortness of breath) to  $\beta$ -lactam antibiotics (e.g. penicillins or cephalosporins) in the past
- If you have a previous history of jaundice or liver problems associated with taking flucloxacillin

**Warning and precautions**

Talk to your doctor or pharmacist before taking Flucloxacillin Capsules

- If you are pregnant or breast-feeding
- 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 50 years of age or older
- If you have other serious illnesses (apart from the infection this medicine is treating).
- If you are taking this medicine for a long time as regular tests of liver and kidney function are advised.
- If you are on a sodium-restricted diet
- you are giving this medicine to a newborn child
- 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.

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.

If any of the conditions above apply to you, please discuss your treatment with your doctor before taking this medicine.

**Other medicines and Flucloxacillin Capsules**

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

- probenecid or sulfapyrazone (used to treat gout)
- methotrexate (a chemotherapy drug)
- oral typhoid vaccine (antibiotics can make this less effective)
- sugammadex (used with general anaesthetics)
- piperacillin (an antibiotic taken by injection)
- warfarin (medicine to prevent blood clotting)
- paracetamol
- other antibiotics (used to treat infections)
- Voriconazole (used against fungal infections)

**Pregnancy and breast-feeding**

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**

Flucloxacillin Capsules should not affect your ability to drive or operate machinery.

**Flucloxacillin Capsules contains sodium**

Each 500mg capsule contain 25mg of sodium. To be taken into consideration by patients on a controlled sodium diet.

**Other special warnings**

Regular monitoring of liver and kidney function should be performed whilst taking Flucloxacillin capsules. If you are having urine tests or blood tests, tell your doctor that you are taking Flucloxacillin Capsules as they may affect the results of these tests.

**3. HOW TO TAKE FLUCLOXACILLIN CAPSULES**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take your flucloxacillin capsules 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 flucloxacillin capsules with a full glass of water (250 ml) and do not lie down immediately after taking your flucloxacillin capsules.

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.

**The recommended dose for:**

**Adults (including the elderly):** 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.

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**Use in children and adolescents**

- Children aged 10-18 years – 250mg four times daily
- Children aged 2-10 years: 125mg four times daily.
- Children under 2 years: 62.5mg four times daily.
- 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 Flucloxacillin capsule than you should**

You should contact your doctor or go to your nearest hospital casualty department immediately, if you or a child have swallowed too much medicine. Take your capsules or the pack with you so that the doctor knows what you have taken. Symptoms of overdose include feeling sick and diarrhoea.

**If you forget to take Flucloxacillin Capsules**

If you miss a dose don't worry. Do not take a double dose to make up for a forgotten dose, just carry on with the normal routine. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**If you stop taking Flucloxacillin 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, this medicine can cause side effects, although not everybody gets them.

**Stop taking Flucloxacillin Capsules and tell your doctor immediately if you experience the following effects:**

- 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).
- Jaundice (yellow colour of 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)

**Tell your doctor immediately if you experience the following:**

**Common: may affect up to 1 in 10 people**

- Diarrhoea, stomach upset and feeling sick - should be mild and wear off after a few days

**Uncommon: may affect up to 1 in 100 people:**

- Rash, urticaria and purpura

**Very rare: may affect to 1 in 10,000 people**

- Inflammation of the kidney
- Blood disorders (neutropenia (including agranulocytosis), thrombocytopenia, haemolytic anaemia).
- Anaphylactic Shock (severe allergic reaction)
- Angioneurotic Oedema (rapid swelling)
- Severe diarrhoea with bleeding, fever and abdominal pain (pseudomembranous colitis).
- Changes in liver function test
- Redness, peeling or blistering of the skin (erythema multiforme)
- Joint or muscle pains or fever (may develop 2 days after starting treatment)
- 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.
- 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 or pharmacist. 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](http://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 FLUCLOXACILLIN CAPSULES**

**KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN**

Store this medicine in a dry place, below 25°C.

Store in the original pack. Keep it in the pack in which it was given to you. Do not transfer your medicine to another container.

Do not use your medicine after the expiry date shown on the label or carton.

The expiry date refers to the last day of that month.

If your doctor tells you to stop taking the capsules, please take any unused medicine back to your pharmacist to be destroyed.

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

**6. CONTENTS OF THE PACK AND OTHER INFORMATION**

**What Flucloxacillin capsule contains**

Each capsule contains 500mg of the active ingredient, flucloxacillin (as flucloxacillin sodium). The other ingredient is magnesium stearate. The capsule shells contain gelatin and the colours indigo carmine (E132) and titanium dioxide (E171). The printing ink contains titanium dioxide (E171), shellac and polysorbate 80.

**What Flucloxacillin Capsules look like and contents of the pack**

The capsule shells are blue. The 500 mg capsules are printed with "fluc 500". They are available in HDPE tablet container with HDPE lid containing 28, 100, 250, 500 and 1000 capsules. Pack sizes of 500 and 1000 capsules are for dispensary pack. They are available in blister pack (opa/Alu/ PVC/Alu and PVC/PVdC/Aluminium) containing 4, 28, 100, 250 and 500 capsules.

Not all pack sizes may be marketed.

**Marketing Authorization Holder**  
RxFarma, Colonial Way, Watford, Hertfordshire, WD24 4YR

**Manufacturer**  
**Flamingo Pharma (UK) Limited**, The Bloc, 38 Springfield Way, Anlaby, Hull, HU10 6RJ.


**Product licence numbers**  
PL 36722/0146

For any information about this medicine, please contact the Marketing Authorisation Holder

The Leaflet was last reviewed in May 2024.

If you would like this leaflet in a different format, please contact the licence holder at the above address.

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