

## **Package leaflet: Information for the patient**

### **Flucloxacillin 500 mg Film-coated Tablets** **Flucloxacillin 1000 mg Film-coated Tablets** **flucloxacillin**

**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 Flucloxacillin Tablets is and what it is used for
2. What you need to know before you take Flucloxacillin Tablets
3. How to take Flucloxacillin Tablets
4. Possible side effects
5. How to store Flucloxacillin Tablets
6. Contents of the pack and other information

#### **1. What Flucloxacillin Tablets 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”.

Flucloxacillin can be used to treat:

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

#### **2. What you need to know before you take Flucloxacillin Tablets**

##### **Do not take this medicine if you:**

- are allergic to flucloxacillin or any other penicillin or cephalosporin antibiotics (such as amoxicillin or cefaclor - see section 4, Possible side effects).
- are allergic to any of the other ingredients of this medicine (listed in section 6, Contents of the pack and other information).
- have ever suffered from jaundice or liver problems after taking flucloxacillin.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking this medicine if you:

- Suffer from kidney problems, as you may require a lower dose than normal
- Suffer from liver problems, as this medicine could cause them to worsen
- Are 50 years of age or older
- Have other serious illnesses (apart from the infection being treated by this medicine)
- Are giving this medicine to a newborn child
- Are on a sodium restricted diet.

- 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.

### **Tests**

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

### **Other medicines and Flucloxacillin Tablets**

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

- Probenecid or sulfinpyrazone (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)
- Other types of antibacterial treatments such as bacteriostatic agents (e.g. chloramphenicol and tetracyclines)
- Voriconazole (used against fungal infections).

Some medicines may affect the way others work. This means medicines you have bought yourself as well as medicines on prescription from a doctor.

### **Flucloxacillin with food and drink**

Flucloxacillin has the best effect if the medicine is taken between meals.

### **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 has no or negligible influence on the ability to drive and use machines.

### **Flucloxacillin Tablets contains sodium**

This medicinal product contains 29.3 mg sodium per 500 mg tablets and 58.6 mg sodium per 1000 mg tablets. To be taken into consideration by patients on a controlled sodium diet.

## **3. How to take Flucloxacillin Tablets**

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

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. If it does not, or you are not sure, check with your doctor or pharmacist.

### **When to take Flucloxacillin Tablets**

Take Flucloxacillin Tablets on an empty stomach, at least 1 hour before or 2 hours after meals. It is important that you take Flucloxacillin Tablets at the right times.

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

#### **How much of Flucloxacillin Tablets to take and when to take it**

The dose will depend on the patient and will be decided by your doctor. However, the usual dose for adults, including the elderly, and children and adolescents over 10 years of age is 1 to 3 g a day in 3 to 4 equally divided doses.

Your pharmacist will explain how to give this medicine to your child.

If you suffer from severe kidney failure your doctor may give you lower or fewer doses.

#### **If you take more of Flucloxacillin Tablets than you should**

If you (or someone else) accidentally take too much of Flucloxacillin Tablets, speak to your doctor or pharmacist immediately. Symptoms of an overdose include feeling or being sick and diarrhoea

#### **If you forget to take Flucloxacillin Tablets**

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 a forgotten tablet.

#### **If you stop taking Flucloxacillin Tablets**

Keep taking Flucloxacillin Tablets 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 are still unwell after taking all the medicine, go and see your doctor.

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

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. If they occur, they are likely to be temporary, and not serious. However, some may be serious and may need medical attention.

#### **STOP taking flucloxacillin and contact your doctor if you experience:**

- Allergy or hypersensitivity including itchy rash, itching, sore mouth or eyes, swelling of the face, lips, throat or tongue or breathing problems
- Severe, bloody diarrhoea (pseudomembranous colitis)
- Blistering or peeling of the skin
- Jaundice (yellow colour in the skin and whites of the eyes), hepatitis (liver inflammation) – can develop some weeks after taking this medicine. If this happens tell your doctor immediately.
- 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).

These are all very rare side effects (may affect up to 1 in 10,000 people).

#### **Tell your doctor if you notice any of the following effects:**

##### **Common (may affect up to 1 in 10 people):**

- Diarrhoea, stomach ache and feeling sick. This should be mild and wear off after a few days. If severe or longer lasting, tell your doctor.

##### **Uncommon (may affect up to 1 in 100 people)**

- Rash, itching, red/purple discolourations on the skin

##### **Very rare (may affect up to 1 in 10,000 people):**

- Kidney problems (may result in difficulty passing urine or blood in urine)
- Unexplained bleeding, bruising or skin discolouration (may be caused by changes in the numbers of blood cells)
- Abnormal breakdown of red blood cells (haemolytic anaemia)
- Joint or muscle pain or fever (may develop 2 days after starting treatment)
- Seizures (convulsions)
- Blood and lymphatic system disorders neutropenia (reduction in white blood cells) including agranulocytosis (serious low level of white blood cells). People with this condition are at very high risk of serious infections due to their suppressed immune system. Patients are advised to report any signs and symptoms of infection to their doctor.
  - Inflammation of the liver, jaundice (yellowing of the skin or whites of the eyes). These effects may be delayed for up to two months after treatment has stopped.
  - Changes in liver function test results (reversible when treatment is discontinued).
  - 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).

**Not known (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.

**Some of these reactions to flucloxacillin can be delayed for up to 2 months after finishing the treatment.**

**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:

Ireland

HPRRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

Malta

ADR Reporting

Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

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

**5. How to store Flucloxacillin Tablets**

Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the label.

Keep this medicine out of the sight and reach of children.

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. Contents of the pack and other information**

**What Flucloxacillin Tablets contains**

The active substance is flucloxacillin as flucloxacillin sodium.

The other ingredients are Microcrystalline Cellulose, povidone K-30, Croscarmellose Sodium, Silica Hydrophobic Colloid, Magnesium stearate, Ethyl cellulose, Dichloromethane, Isopropyl alcohol, HPMC 2910/Hypromellose, Titanium Dioxide, Macrogol/PEG, and Paraffin.

**What your medicine looks like and contents of the pack**

500mg: White to off white capsule shaped film coated tablet debossed with 'FL|500' on one side and break line on other side.

1000mg: White to off white oval shaped film coated tablet, debossed with 'FL|1G' on one side and break line on other side.

Strip of 10 tablets per pack

Blister of 10 tablets per pack

HDPE bottle of 100 tablets per container (500mg)

HDPE bottle of 75 tablets per container (1000mg)

**Marketing Authorisation Holder**

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