

## **PATIENT INFORMATION LEAFLET**

### **FLUCLOXACILLIN 250MG CAPSULES**

### **FLUCLOXACILLIN 500MG CAPSULES**

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

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or pharmacist (chemist).

This medicine has been prescribed for you personally and you should 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 your medicine is and what it is used for
2. Before you take your medicine
3. How to take your medicine
4. Possible side effects of your medicine
5. How to store your medicine
6. Further information

#### **1. WHAT YOUR MEDICINE IS AND WHAT IT IS 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 is used to treat:

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

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

#### **2. BEFORE YOU TAKE YOUR MEDICINE**

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

- You have ever had an allergic reaction to flucloxacillin or any other penicillin antibiotics (see symptoms section 4).
- You have ever had an allergic reaction to any of the other ingredients of this medicine – see list of ingredients in section 6, Further information.
- You have suffered previously from liver problems (e.g. jaundice) after taking flucloxacillin.

##### **Take special care with your medicine**

Check with your doctor or pharmacist before taking this medicine if:

- You suffer from kidney problems, as you may require a lower dose than normal
- You suffer from liver problems, as this medicine could cause them to worsen
- You are 50 years of age or older
- You have other serious illnesses (apart from the infection this medicine is treating)

- You are taking this medicine for a long time as regular tests of liver and kidney function is advised
- You are on a sodium restricted diet.

### **Taking other medicines**

Check with your doctor or pharmacist before taking this medicine if you are taking any other medicines, especially:

- Probenecid or sulfinpyrazone (used to treat gout)
- Methotrexate (a chemotherapy drug)
- The contraceptive pill as antibiotics can make these less effective (you will need to use extra precautions such as condoms while taking flucloxacillin and for a full 7 days after you finish taking it)
- Oral typhoid vaccine (antibiotics can make this less effective)
- Sugammadex (used with general anaesthetics)
- Piperacillin (an antibiotic taken by injection)

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 medicines on prescription from a doctor.

### **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.

### **Important information about some of the ingredients in your medicine**

This medicine contains approximately 52.3mg sodium per g. Check with your doctor before taking this medicine if you are on a sodium restricted diet.

## **3. HOW TO TAKE YOUR MEDICINE**

Follow all directions given to you by your doctor or pharmacist. 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.

Take this medicine when your stomach is empty. This means an hour before food or 2 hours after food. The dose will depend on the patient and will be decided by your doctor. However, the usual doses for each age group are:

#### **Adults (including the elderly)**

- The usual dose is 250mg four times a day
- Bone or heart infection: Up to 8g daily, in divided doses at six to eight hours apart.
- Surgical prophylaxis: 1 to 2g IV at induction of anaesthesia followed by 500mg every six hours for up to 72 hours.

#### **Children**

**Children (10-18 years of age):** Same as adult dose

**Children (2-10 years of age):** Half the adult dose

**Children under 2 years of age:** Quarter the adult dose

**Patients with kidney problems**

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

**If you take more of your medicine than you should**

If you (or somebody else) accidentally takes too much of your medicine, speak to your doctor or pharmacist immediately.

**If you forget to take your medicine**

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.

**If you stop taking your medicine**

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

**4. POSSIBLE SIDE EFFECTS OF YOUR MEDICINE**

Like all medicines, Flucloxacillin Capsules may cause unwanted side effects. If they occur, they are likely to be temporary, and not serious. However, some may be serious and need medical attention.

**STOP taking Flucloxacillin Capsules 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, possibly bloody, diarrhoea
- jaundice (yellow colour in the skin and whites of the eyes)  
(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).

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

**Common** (occurs in less than 1 in 10 users but more than 1 in 100 users):

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

**Very rare** (occurs in less than 1 in 10,000 users):

- difficulty passing water or blood in the urine (may be a sign of inflammation of the kidney)
- unusual bleeding or bruising, anaemia (may be caused by changes in the numbers of blood cells)
- joint or muscle pains or fever (may develop 2 days after starting treatment).

Check with your doctor if you have any problems while taking this medicine, even if you think the problems are not connected with the medicine, or are not listed in this leaflet.

**5. HOW TO STORE YOUR MEDICINE**

Do not use this medicine after the expiry date shown on the label.

## **KEEP OUT OF THE REACH AND SIGHT OF CHILDREN**

Securitainers: Store below 25°C. Store in the original package. Keep the container tightly closed to protect from light and moisture.

Blister Packs: Store below 25°C. Do not open the foil pouch until ready to use the product. Once opened the foil pouch may be discarded. Store the product in the outer carton to protect from light and moisture. Return any left-over medicine to the pharmacist. 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 protect the environment.

### **6. FURTHER INFORMATION**

#### **What Flucloxacillin Capsules contain**

Active ingredient: flucloxacillin as flucloxacillin sodium

Other ingredients: sodium starch glycolate, magnesium stearate, red iron oxide (E172), yellow iron oxide (E172), black iron oxide (E172), titanium dioxide (E171) and gelatin. Please see further information on sodium in section 2.

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

250mg Capsules are opaque caramel and grey, printed with 'FXN 250' in black ink. The capsules contain a granular off-white powder.

500mg Capsules are opaque caramel and grey, printed with 'FXN 500' in black ink. The capsules contain a granular off-white powder.

Both strengths are available in the following pack sizes:

Securitainers are available in pack sizes of 15, 18, 20, 21, 28, 30, 50, 100, 250 & 500 capsules.

Blister packs are available in pack sizes of 15, 18, 20, 21, 28, 30, 50, 100, 250 & 500 capsules.

Not all pack sizes may be marketed.

#### **The licence holder and manufacturer is:**

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

**Distributed by:** Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, UK

PL06453/0015

PL06453/0016

This leaflet was revised September 2012.