PACKAGE LEAFLET: INFORMATION FOR THE USER

Flucloxacillin 2 g, Powder for Solution for Injection or Infusion
Flucloxacillin as Flucloxacillin Sodium

Read all of this leaflet carefully before you start using 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

The name of your medicine is "**Flucloxacillin 2g, Powder for Solution for Injection or Infusion**" (referred to as Flucloxacillin 2g Injection throughout this leaflet).

1. WHAT FLUCLOXACILLIN IS AND WHAT IT IS USED FOR

Your medicine contains the active substance flucloxacillin (as flucloxacillin sodium), which is one of a group of medicines called "penicillins". These medicines are also known as "antibiotics" and they work by killing the bacteria that cause infections.

Flucloxacillin 2g injection is used to treat
- heart infections
- bones and joints infections

Flucloxacillin 2g injection can also be used to prevent infections during major surgery, particularly heart or orthopaedic surgery.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN FLUCLOXACILLIN INJECTION

You should not be given Flucloxacillin Injection if:
- You are allergic to flucloxacillin, penicillin, cephalosporins or other antibiotics (see symptoms in section 4)
- You have had jaundice (your skin and the whites of your eyes turn yellow) or you have had other liver problems when you have been given flucloxacillin previously.

You must tell your doctor or nurse if any of these apply to you.

Flucloxacillin should not be given into the eye or under the eye lids.

Warnings and precautions
Talk to your doctor or nurse before you are given Flucloxacillin injection if any of the following apply to you:
- You have ever had a skin rash or swelling of the face or neck when taking an antibiotic
- You have any serious illness other than this infection
- You are being treated for liver or kidney problems or heart failure (as you may require a lower dose than normal)

- You are on a low sodium diet (See "Flucloxacillin injection contains sodium")
- You are being treated for an infection such as syphilis or leptospirosis
- You are aged 50 or above
- You have porphyria (your doctor will have told you)
- You are a known carrier of the HLA-B* 5701 allele
- 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 together with paracetamol, particularly in certain groups of patients at risk e.g. patients with severe kidney 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.

Special care is essential in the newborn because of the risk of jaundice and high blood levels of flucloxacillin.

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 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
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines, especially:
- Probenecid (used for the treatment of gout)
- Methotrexate (used to treat some tumours)
- Chloramphenicol or tetracycline (anti-bacterial medicines).

If you are being treated with Flucloxacillin, this can affect some blood and urine test results.

Pregnancy and breast-feeding
Tell the doctor or nurse if you are pregnant, think you might be pregnant or if you are breast feeding before you are given this medicine.

Driving and using machines
This medicine has no known effects on the ability to drive or use machines.

Flucloxacillin injection contains sodium
This medicine contains 104 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 5.2% of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW FLUCLOXACILLIN INJECTION IS GIVEN

Your doctor or nurse will prepare your injection in the form of a liquid. They will inject this into a vein (intravenous).

Your doctor will decide how much you need each day and how often the injections should be given. The usual doses are as follows.

Adults and children over 12 years old:
For infections of the bones and joints (osteomyelitis), or the heart (endocarditis) – up to 8 g daily can be given, in divided doses six to eight hourly.

Premature infants, neonates, sucklings and infants
Other pharmaceutical forms/strengths may be more appropriate for administration to this population.

Use in children and adolescents
Under 12 years of age
The recommended dose is 25 to 50 mg/kg/24 hours administered in three to four equally divided doses by i.v. injection.
In cases of severe infections: Up to 100 mg/kg/24 hours in three to four divided doses.
No single bolus injection or infusion should exceed 33 mg/kg.

Aged 10 to 14 years
The recommended dose is a daily dose of 1.5 g to 2 g.

Aged 6 to 10 years:
0.75 g to 1.5 g, divided into three to four equal doses.

Severe kidney disease
Your doctor may reduce your dose, maximum dose in adults is 1g every 8 to 12 hours.

These doses can be increased in more serious infections.

To prevent infections after an operation, the usual dose is 1 to 2g before the operation when you are given your anaesthetic. This is then followed by 500mg four times a day for up to three days after your operation.

If you think you have missed an injection, or had too many injections, speak to your doctor or nurse.

If you are given more of this medicine than you should
This is unlikely to happen but if it does, the doctor will treat any symptoms that follow.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Flucloxacillin Injection can cause side effects, although not everybody gets them.

STOP taking Flucloxacillin Injection and contact your doctor straight away if you experience any of the following side effects:
- Severe diarrhoea with bleeding
- Your skin or the whites of your eyes turn yellow
- Your urine becomes darker or your faeces become paler
- Any unexplained bleeding or bruising or skin discolouration
- Convulsions (fits) at high doses
- Tiredness, breathlessness, light-headedness, a rapid weak pulse, palpitations or headaches, these may be signs of the destruction of red blood cells (causing anaemia)
- Skin rash and itching
- Blistering of the skin, mouth, eyes or genitals
- Any sudden wheeziness, difficulty in breathing or dizziness
- Any swelling of the face, neck or tongue
- Serious skin reactions
- A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis).

Some of these reactions can be delayed for several weeks after finishing treatment.

The following side effects may also occur. Tell your doctor if any of these become troublesome.

Common side effects (may affect up to 1 in 10 people)
- Minor gastrointestinal disturbances e.g stomach upset or diarrhoea.

Very rare side effects (may affect up to 1 in 10,000 people)
- Reduction (reversible) in blood cell counts which makes infections more likely
- Inflammation of the kidney, bowel and/or liver. Liver problems may be severe and very rarely deaths have been reported (mainly in people with pre-existing liver problems or over 50's)
- Joint pain, muscle pain. This may develop after 2 days or more from the start of treatment
- Fever. This may develop after 2 days or more from the start of treatment
- Blood and fluid abnormality (high anion gap metabolic acidosis) which occurs when there is an increase in plasma acidity when flucloxacillin is used together with paracetamol, particularly in the presence of risk factors (see "Warnings and precautions" above).

Not known (frequency cannot be estimated from the available data)
- Low potassium levels in the blood (hypokalaemia), which can cause muscle weakness, twitching or abnormal heart rhythm.

Reporting of side effects
If you get any side effects, talk to your doctor, nurse, 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 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 INJECTION

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.
Store vials below 25°C. Your doctor, pharmacist or nurse will know how to store Flucloxacillin Injection properly.
Do not use this medicine if you notice signs of deterioration.
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 injection contains
Each vial contains 2g of Flucloxacillin (as flucloxacillin sodium). There are no other ingredients.

What Flucloxacillin injection looks like and contents of the pack:
Flucloxacillin injection is a white powder in a glass vial.
Each carton contains 1, 5, 10, 20 or 50 glass vials.
Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Ibigen S.r.l.
Via Fossignano 2,
04011 Aprilia (LT)
Italy

Manufacturer:
Istituto Biochimico Italiano S.p.A.
Via Fossignano 2, 04011 Aprilia (LT)
Italy

This leaflet was last revised in February 2021.

INFORMATION FOR THE HEALTHCARE PROFESSIONAL

The following information is intended for medical or healthcare professionals only.

Incompatibilities

- This medicine must not be mixed with other medicines except those mentioned below (Instructions for use and handling)
- Flucloxacillin should not be mixed with blood products or other proteinaceous fluids (e.g. protein hydrolysates) or with intravenous lipid emulsions
- If flucloxacillin is prescribed concurrently with an aminoglycoside, the two antibiotics should not be mixed in the syringe, intravenous fluid container or giving set as precipitation may occur.

Shelf life 36 months unopened. After opening: 24 hours.

Special precautions for storage Store below 25°C.
Reconstituted solution: From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C unless reconstitution/ dilution has taken place in controlled and validated aseptic conditions.

Administration
Intravenous: Dissolve 2 g in 40 ml Water for Injections (final volume: 41.5 ml). Administer by slow intravenous injection.
Flucloxacillin may also be added to infusion fluids or injected, suitably diluted, into the drip tube.

Instructions for use and handling
Contact with flucloxacillin should be avoided since skin sensitisation may occur.

Flucloxacillin powder for solution may be added to the following intravenous fluids: Water for Injections, sodium chloride 0.9%, glucose 5%, sodium chloride 0.18% with glucose 4%, Compound Sodium Lactate Intravenous Infusion (Ringer-Lactate solution; Hartmann's Solution).

N.B. FLUCLOXACILLIN VIALS ARE NOT SUITABLE FOR MULTIDOSE USE.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Posology and method of administration
Depends on the age, weight and renal function of the patient, as well as the severity of the infection.

Adults and children over 12 years old:

Osteomyelitis, endocarditis - Up to 8 g daily, in divided doses six to eight hourly.
Surgical prophylaxis - 1 to 2 g IV at induction of anaesthesia followed by 500 mg six hourly IV, IM or orally for up to 72 hours.

Paediatric population
Premature infants, neonates, sucklings and infants
Other pharmaceutical forms/strengths may be more appropriate for administration to this population.

Children under 12 years of age
The recommended dose is 25 to 50 mg/kg/24 hours administered in three to four equally divided doses by i.v. injection.

In cases of severe infections: Up to 100 mg/kg/24 hours in three to four divided doses.
No single bolus injection or infusion should exceed 33 mg/kg.

Children aged 10 to 14 years usually receive a daily dose of 1.5 g to 2 g and children aged 6 to 10 years 0.75 g to 1.5 g, divided into three to four equal doses.

Renal impairment:
In common with other penicillins, flucloxacillin usage in patients with renal impairment does not usually require dosage reduction. However, in the presence of severe renal failure (creatinine clearance < 10 ml/min) a reduction in dose or an extension of dose interval should be considered. The maximum recommended dose in adults is 1 g every 8 to 12 hours.
Flucloxacillin is not significantly removed by dialysis and hence no supplementary dosages need to be administered either during, or at the end of the dialysis period.

Hepatic impairment
No dose reduction is necessary in patients with reduced hepatic function.