

PACKAGE LEAFLET: INFORMATION FOR THE USER

Flucloxacillin 250mg, 500mg or 1g, 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 250mg, 500mg, 1g Powder for Solution for Injection or Infusion**” (referred to as Flucloxacillin 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 injection is used to treat a wide range of bacterial infections which may include those affecting:

- The chest (pneumonia, emphysema and lung abscess)
- Tonsils (tonsillitis, quinsy)
- Pharynx (pharyngitis)
- Sinuses (sinusitis)
- Ears (otitis media and otitis externa)
- Skin and soft tissue (boils, abscesses, carbuncles, impetigo, cellulites, furunculosis, ulcers and acne)
- Wounds and burns
- Heart (endocarditis)
- Bones and joints (osteomyelitis)
- Membranes of the brain (meningitis)
- Gut (enteritis)
- Blood (Septicaemia)
- Kidney, bladder or the urethra (the tube which carries urine from the bladder).

Flucloxacillin injection can also be used to prevent infections following skin grafts or during major surgical procedures, particularly in 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 problems (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

250mg vial: This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially “sodium free”.

500mg/1g vial: These medicines contain 26mg/52mg sodium (main component of cooking/table salt) in each 500mg and 1g vial respectively. This is equivalent to 1.3% and 2.6% 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 muscle (intramuscular) or into a vein (intravenous). It can also be given to you by injection into a joint, or injection into the lining of the lung, or by breathing in the medicine from a mask (nebuliser).

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:

The recommended total daily dosage of 1 g – 6 g administered in 3-6 divided doses, by intravenous (i.v.) or intramuscular (i.m). injection.

No intramuscular single bolus injection should exceed 2 g.

The maximum dose of 12 g per day should not be exceeded.

In cases of severe infections: Up to 8 g per day administered in three to four infusions (over 20 to 30 min).

Premature infants, neonates, sucklings and infants

Other pharmaceutical forms/strengths may be more appropriate for administration to this population.

For infections of the bones and joints (osteomyelitis) or the heart (endocarditis) – up to 8g daily can be given in divided doses, every 6 to 8 hours.

Flucloxacillin may be administered by other routes, together with systemic therapy (proportionally lower doses should be given in children)

- by injection into the lining of the lung: 250 mg once daily
- by breathing in the medicine from a mask (nebuliser): 125 mg to 250 mg four times a day
- by injection into a joint: – 250 mg to 500 mg once daily

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.m. or 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 discoloration.

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 250mg, 500mg or 1g 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

Intramuscular: Add 1.5 ml Water for Injections to 250 mg vial contents. Add 2 ml Water for Injections to 500 mg vial contents.

Intravenous: Dissolve 250-500 mg in 5-10 ml Water for Injections. Dissolve 1 g in 15-20 ml Water for Injections. Administer by slow intravenous injection (three to four minutes). Flucloxacillin may also be added to infusion fluids or injected, suitably diluted, into the drip tube over a period of three to four minutes.

Intrapleural: Dissolve 250 mg in 5-10 ml Water for Injections.

Intra-articular: Dissolve 250-500 mg in up to 5 ml Water for Injections or 0.5% lidocaine hydrochloride solution.

Nebuliser solution: Dissolve 125-250 mg of the vial contents in 3 ml sterile water.

The following displacement volumes have been determined:

Strength	Reconstitution volume	Displacement volume (approximate)
250 mg	1.5 – 10 ml	0.2 ml
500 mg	2 – 10 ml	0.35 ml
1 g	15 – 20 ml	0.6 ml

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.

Usual adult dosage (including elderly patients)

Adults and adolescents over 12 years of age

Total daily dosage of 1 g - 6 g administered in 3-6 divided doses, by i.v. or i.m. injection.

In cases of severe infections: Up to 8 g per day administered in three to four infusions (over 20 to 30 min).

No intramuscular single bolus injection should exceed 2 g.

The maximum dose of 12 g per day should not be exceeded.

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.

Flucloxacillin may be administered by other routes in conjunction with systemic therapy. (Proportionately lower doses should be given in children.)

Intrapleural - 250 mg once daily.

By nebuliser - 125 to 250 mg four times a day.

Intra-articular - 250 to 500 mg once daily.

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.m. or 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.