Package leaflet: Information for the patient

Flucloxacillin 500mg and 1000mg powder for solution for injection or infusion

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 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.

The full name of this product is **Flucloxacillin 500 mg or 1000mg , powder for solution for injection or infusion**, but within the leaflet it will be referred to as **Flucloxacillin**.

What is in this leaflet

1. What Flucloxacillin is and what it is used for

Flucloxacillin is an antibiotic used to treat infections by killing the bacteria that cause them. It belongs to a group of antibiotics called "penicillins".

Flucloxacillin is available in two strengths. Each vial contains 500mg or 1000mg flucloxacillin powder for reconstitution for injection.

Flucloxacillin is used for the treatment of a range of bacterial infections including bone infections (osteomyelitis) and infections within the lining of the heart (endocarditis). Flucloxacillin can also be used to prevent infections that can occur during major surgical operations, such as heart (cardiothoracic surgery) or bone, joint and muscle operations (orthopaedic surgery).

2. What you need to know before you use Flucloxacillin

You should not be given Flucloxacillin:
- if you are allergic to flucloxacillin
- if you are allergic to penicillins, cephalosporins and other antibiotics
- if you have had jaundice (yellow skin and white of eyes) or 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 pharmacist before you are given flucloxacillin,
- if you have ever had a skin rash or swelling of the face or neck when taking an antibiotic
- if you ever had a serious complaint when taking an antibiotic
- if you are being treated for liver problems
- if you are being treated for kidney problems or gout
- if you are on a low sodium diet
- if you are 50 years old or over
- if you have porphyria
- if you have any serious illness, other than this infection
- if you are giving this medicine to a newborn child
- if you are taking or will be taking paracetamol. When flucloxacillin is used together with paracetamol there is an increased risk of a blood abnormality called high anion gap metabolic acidosis, a condition in which the body produces too much acid or the kidneys do not remove enough acid from the body. Patients at increased risk are those with poor kidney function, blood poisoning, poor nutrition and especially when the maximum daily doses of paracetamol are used. (Your doctor will need to do a blood test to confirm this.) High anion gap metabolic acidosis is a serious disease that must have urgent treatment.
- The use of flucloxacillin, especially in high doses, may reduce 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 above applies to you, your doctor may prescribe a different medicine or a different dose of flucloxacillin.

Other medicines and Flucloxacillin
Tell your doctor or nurse if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription. Especially:
- methotrexate, reduced excretion may occur with flucloxacillin (increased risk of toxicity)
- probenecid (used to treat gout)
- please tell your doctor if you are taking other antibiotics when prescribed flucloxacillin, as it may affect the action of flucloxacillin.
- voriconazole (used against fungal infections)

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before taking this medicine.

Driving and using machines
There should be no effect on the ability to drive or operate machinery.

Tests
Regular monitoring of liver and kidney function should be performed during prolonged treatments. Tell your doctor that you are taking flucloxacillin if you are having liver function tests as flucloxacillin may affect the results. If you are having a blood test, you should mention to the doctor or nurse that you are taking flucloxacillin because the antibiotic might affect the blood test results.

Flucloxacillin contains sodium
This medicinal product contains approximately 51 mg sodium per g. This should be included in the daily allowance of patients on a sodium restricted diet.

3. How to use Flucloxacillin

Your doctor or nurse will give you this medicine by injection into a muscle (intramuscular) or injection into a vein (intravenous). It can also be given to you by injection into a joint (intra- articular)

or injection into the lining of the lung (intrapleural), or by breathing in the medicine from a mask (nebuliser).

Your doctor will decide on the dose and the duration of treatment. This will depend on the severity and type of infection you have.

If you have severe kidney failure you may be given a lower dose or you may receive your doses less frequently.

The recommended dose for treating infections intramuscularly or intravenously is:

Adults and adolescents over 14 years:
The usual dose is 250 mg to 1 g every six hours.
For severe infections: up to 8 g daily can be given, administered in three to four infusions (over 20-30 minutes).
Doses of up to 8g a day may be required for infections of the bones and joints (osteomyelitis) or the heart (endocarditis).
To prevent infections after an operation the usual dose is 1 to 2 g 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.

Children under 14 years:
25-50 mg per kg body weight in 24 hours. This will be given in three or four divided doses.
Children aged 10-14 years usually receive a daily dose of 1.5 g – 2 g in three to four divided doses.
Children aged 6-10 years usually receive a daily dose of 0.75 g – 1.5 g in three to four divided doses.
For severe infections: Up to 100 mg per kg body weight in 24 hours. This will be given in three or four divided doses each day.

Flucloxacillin may be administered by other routes, together with systemic therapy:
- by injection into the lining of the lung (intrapleural): 250mg once daily,
- by injection into a joint (intra-articular): up to 250 - 500 mg once daily,
- inhalation by nebulizer: 125 mg – 250 mg four times a day.

If you are given more Flucloxacillin than you should
As this medicine will normally be given to you by a nurse or a doctor, it is unlikely you will be given too much, but if you think you have been given too much flucloxacillin tell your doctor or nurse immediately. Signs may be nausea, vomiting and diarrhoea.

If you think you have missed a dose of Flucloxacillin
As this medicine will normally be given to you by a nurse or a doctor, it is unlikely you will miss a dose, but if you have any concerns discuss this with your doctor or nurse.

If you have any further questions on the use of this medicine, ask your doctor or healthcare professional.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Prolonged treatment with flucloxacillin may result in increased growth of resistant organisms.

If you notice any of the following side effects soon after receiving this medicine, tell your doctor or nurse immediately. If you get them you may have had a serious allergic reaction or other type of reaction to this medicine. You may need urgent medical attention, if you have:

- Stomach pain or diarrhoea (possibly with bleeding)
- Your skin or the white of your eyes turn yellow
- Your urine becomes darker or your faeces become paler
- Any unexplained bleeding, bruising or skin discolouration
- Skin rash and itching
- Blistering of the skin, mouth, eyes and 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)
- Severe bloody diarrhoea (pseudomembranous colitis)

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

Common side effects (may affect up to 1 in 10 people):
- Stomach upset or diarrhoea

Very rare (may affect up to 1 in 10,000 people):
- Reduction in blood cell counts which makes infections more likely
- Inflammation of the kidney which can cause swollen ankles or high blood pressure
- Joint pain, muscle pain or fever. This may develop after 2 days or more from the start of treatment.
- Convulsions ("fits") in patients taking high doses.
- High anion gap metabolic acidosis in patients taking flucloxacillin together with paracetamol (see section 2).

Not known (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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

UK patients can report side effects directly to MHRA 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.

Irish patients can report side effects directly to HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. How to store Flucloxacillin

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

Do not store above 25ºC.

Do not use this medicine after the expiry date which is stated on the vial and outer carton after the abbreviation EXP. The expiry date refers to the last day of that month.

Reconstituted solutions for IM or direct IV injection should normally be administered within 30 minutes of preparation.

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 contains

- The active substance is flucloxacillin. Each vial contains either 500 mg or 1000 mg flucloxacillin as flucloxacillin sodium.
- There are no other ingredients.

What Flucloxacillin looks like and contents of the pack

Flucloxacillin 500mg and 1000mg powder for solution for injection or infusion is a fine white powder. Flucloxacillin is supplied in packs of 10 vials in a carton with a package leaflet.

Marketing Authorisation Holder for UK:
Esteve Pharmaceuticals Ltd
The Courtyard Barns
Choke Lane
Maidenhead
Berkshire SL6 6PT
UK

Marketing Authorisation Holder for Ireland:
Esteve Pharmaceuticals GmbH,
Hohenzollerndamm 150-151,
14199 Berlin,
Germany.

Manufacturer:
Antibiotice SA
1 Valea Lupului Street
707410 Iasi
Romania

This leaflet was last revised in May 2023.

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

Incompatibilities
- This medicinal product must not be mixed with other medicinal products except those mentioned below.
- 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; precipitation may occur.

Preparation and administration of Flucloxacillin reconstituted solutions
Routes of administration: intramuscular, intravenous, intrapleural, intra-articular and inhalation.

Flucloxacillin may be added to most intravenous fluids (e.g. Water for Injections, sodium chloride 0.9%, glucose 5%, sodium chloride 0.18% with glucose 4%, Hartmann's solution, Dextran 40 (10%)

Intravenous Infusion in NaCl (0.9%) intravenous infusion, Dextran 40 (10%) Intravenous Infusion in glucose (5%) intravenous infusion).

Intramuscular: Add 2 ml Water for Injections to 500 mg vial contents. Add 3.0 ml Water for Injections to 1 g vial contents.

Intravenous: Dissolve 250-500 mg in 5-10 ml Water for Injections. Dissolve 1g in 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 1.0% lidocaine hydrochloride solution.

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

Any unused product or waste should be disposed of in accordance with local requirements.

How to store
Reconstituted solutions for IM or direct IV injection should normally be administered within 30 minutes of preparation.

Posology and method of administration
The usual adult dosage (including the elderly) is as follows:

By slow intravenous injection or by infusion: 250 mg to 1 g every six hours. These doses may be doubled in severe infections.
Osteomyelitis: Up to 8 g daily divided in 3 to 4 divided doses
Endocarditis: 8 g daily in four divided doses in patients weighing up to 85 kg, and 12 g daily in 6 divided doses may be used in those weighing more.
*During surgical prophylaxis***,** 1 to 2 g intravenously at induction of anaesthesia followed by 500 mg six hourly intravenously or intramuscularly for up to 48 hours.

By intramuscular injection: 250 mg four times daily.
By intrapleural injection: 250 mg once daily.
By nebuliser: 125 to 250 mg four times daily.
By intra-articular injection: 250 to 500 mg once daily.

No single bolus injection or infusion should exceed 2 g.
The maximum dose of 12 g per day should not be exceeded.

<u>Paediatric population:</u>

Children under 14 years of age
25 to 50 mg/kg/24 hours administered in three to four equally divided doses by IM or IV injection.
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.
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.

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 is 1 g every 8 to 12 hours. Flucloxacillin is not significantly removed by dialysis and hence no supplementary dosages need be administered either during, or at the end of the dialysis period.

Hepatic impairment
Dose reduction in patients with reduced hepatic function is not necessary.
