



Flucloxacillin 1 g

powder for solution for injection

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The full name of this product is **Flucloxacillin 1 g, powder for solution for injection** 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
2. What you need to know before you are given Flucloxacillin
3. How Flucloxacillin is given
4. Possible side effects
5. How to store Flucloxacillin
6. Contents of the pack and other information

1. What Flucloxacillin is and what it is used for

Flucloxacillin belongs to a group of medicines called penicillins, which are antibiotics. These medicines work by killing bacteria that cause infections.

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

2. What you need to know before you are given Flucloxacillin

You should not be given Flucloxacillin if:

- are allergic to flucloxacillin, cephalosporins, penicillin, or any other β -lactam antibiotic,
- have had jaundice (yellow skin and whites of eyes) or other liver problems when you have been given Flucloxacillin previously.

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

Warnings and precautions:

Talk to your doctor before being given Flucloxacillin if you:

- have had any allergies especially to any other drugs (particularly penicillin),
- are suffering from liver or kidney problems,
- have heart failure,
- have syphilis (a sexually transmitted disease) or leptospirosis (Weil's disease),
- suffer from porphyria (an inherited blood disorder).

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.

Special care should be taken in newborn babies to avoid overdose or high levels of a chemical in the blood which can lead to brain damage.

If any of the above statements apply to you, speak to your doctor or nurse before you are given Flucloxacillin.

Other medicines and Flucloxacillin:

Taking another medicine while you are being given Flucloxacillin can affect how it or the other medicine works. Please inform your doctor or nurse if you are taking or have recently taken any other medicines, even those you may have bought yourself without a prescription.

Please particularly check with your doctor if you are taking or need to take any of the following:

- certain other "bacteriostatic" antibiotics (antibiotics that stop bacteria growing but do not kill them), such as chloramphenicol and tetracycline
- methotrexate, a drug used in the treatment of cancer
- oral contraceptives that contain oestrogen e.g. the combined pill. If you are using this type of medicine you should take additional precautions to prevent pregnancy while you are receiving Flucloxacillin and for at least seven days afterwards. If these seven days run beyond the end of a packet of contraceptive pills you should start the next packet immediately without a break
- Probenecid, a drug used for the treatment of gout
- If 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 concomitantly with paracetamol, particularly in certain groups of patients at risk, e.g. patients with severe renal impairment, spies 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.

Flucloxacillin may interfere with various laboratory tests.

Pregnancy and breast-feeding

You should let your doctor know immediately if you are pregnant or trying for a baby before this medicine is administered.

You should not breast-feed whilst being given Flucloxacillin. You should let your doctor know if you are breast-feeding or want to start breast-feeding while you are having treatment with Flucloxacillin.

Driving and using machines

Flucloxacillin is not known to affect your ability to drive or use machines.

Flucloxacillin contains sodium

Flucloxacillin 1 g contains 2,19 mmol sodium per vial. To be taken into consideration by patients on a controlled sodium diet.

3. How Flucloxacillin is given

Your medicine will usually be given to you by injection into the muscle (intramuscular) or injection into a vein (intravenous). Flucloxacillin should not be administered into the eye.

Your doctor will decide how much you need each day and how often the injections should be given.

The usual dose for treating infection is:

Adults and children over 10 years:
intramuscular 250 mg four times a day
intravenous 250 mg to 1 g four times a day

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.

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

The usual dose for children aged two to ten years is half the adult dose.

The usual dose for children under two years old is a quarter of the adult dose.

Special care should be taken in newborn babies to prevent the risk of overdosing.

These doses can be increased in more serious infections.

If you have severe kidney failure you may be given a lower dose or you may receive your doses less frequently. Your doctor will decide the dose that is best for you. If you do not understand, or are in any doubt, ask your doctor or nurse. If you think you have missed an injection, or had too many injections, speak to your doctor or nurse

4. Possible side effects

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

Tell your doctor immediately if you notice any of the following side effects as they may be a sign of an allergic or sensitive reaction:

- rash
- itching
- redness and blistering of the skin
- fever
- swelling of the face, throat or hands
- difficulty breathing
- anaemia
- kidney problems
- skin condition that causes painful blisters and sores of the skin and mucous membranes, especially in the mouth (also known as Steven-Johnson syndrome).

The occurrence at the treatment initiation of a generalized redness and blistering of the skin associated with pustula and fever may be a symptom of acute generalized exanthematous pustulosis (AGEP).

Also tell your doctor immediately if you develop any of the following:

- tenderness of the upper abdomen which may indicate inflammation of the liver or jaundice (yellow skin and whites of eyes)
- severe diarrhoea. Treatment with Flucloxacillin can affect the normal bacteria in the gut, causing a new infection (pseudomembranous colitis)

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

Hepatitis (inflammation of the liver) and jaundice may be long lasting. They are more likely in the elderly or patients with serious underlying diseases.

Other side effects may occur:

- minor gastrointestinal disturbances: nausea, vomiting, diarrhea
- blood disorders
- aching joints
- muscle aches
- blood disorders (low number of white blood cells, low number of platelets, low number of red blood cells)
- very rare (may affect up to 1 in 10,000 people) 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) cases of 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. You can also report side effects directly via the national reporting systems listed below.

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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.

Flucloxacillin does not require any special storage conditions. The reconstituted solution should be used immediately. If not used immediately, solution can be kept no longer than 24 hours at 2 to 8°C.

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

The expiry date refers to the last day of that month.

Do not use this medicine if you notice signs of deterioration such as going cloudy.

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 packs and other information what Flucloxacillin contains

What FLUCLOXACILLIN contains

The active substance in Flucloxacillin is flucloxacillin sodium. Each vial contains 1 g of flucloxacillin (equivalent to 1,08 g of flucloxacillin sodium).

What FLUCLOXACILLIN looks like and contents of the pack

Flucloxacillin is supplied in glass vials in packs of 1, 10, 25 and 50.

Flucloxacillin is supplied as a white or almost white powder.

Marketing Authorisation Holder and Manufacturer

Marketing authorization holder

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Manufacturer

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