

Package leaflet: Information for the user

Flucloxacilline Eberth 1 g poeder voor oplossing voor injectie/infusie Flucloxacilline Eberth 2 g poeder voor oplossing voor injectie/infusie flucloxacillin

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 healthcare professional.
- If you get any side effects, talk to your doctor, pharmacist or healthcare professional. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Flucloxacillin Eberth is and what it is used for
2. What you need to know before you are given Flucloxacillin Eberth
3. How Flucloxacillin Eberth is given
4. Possible side effects
5. How to store Flucloxacillin Eberth
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1. What Flucloxacillin Eberth is and what it is used for

Flucloxacillin Eberth is an antibiotic belonging to a class of antibiotics called beta-lactamase resistant penicillins. The active substance is flucloxacillin.

Flucloxacillin works by killing bacteria that cause infection. It only works with specific strains of bacteria.

Flucloxacillin Eberth is used to treat infections such as:

- Skin and soft tissue infections, like abscesses, cellulitis (inflammation of tissue below the skin), infected burns, pustular dermatitis (impetigo)
- Upper respiratory tract infections, like sore throat (pharyngitis, tonsillitis), inflammation of the sinuses (sinusitis)
- Lower respiratory tract infections, like pneumonia, lung abscess, bronchopneumonia
- Bone and joint infections, like bone and bone marrow infections (osteomyelitis), arthritis
- Inflammation of the lining of the heart and its valves (endocarditis)

Flucloxacillin Eberth is also used to prevent infections that occur during heart and lung surgery (valve prostheses, artery prostheses) and in bone, joint and muscle surgery (orthopaedic surgery) because of the dominant pathogenic potential of staphylococci during such surgical procedures.

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

Flucloxacillin Eberth must not be given

- if you are allergic to flucloxacillin or other betalactam antibiotics (e.g. penicillins, cephalosporins),
- if you have previous history of liver problems from taking flucloxacillin.
- for ocular or subconjunctival (eye) administration.
- into the spinal canal containing the spinal cord.

Warnings and precautions

Talk to your doctor or pharmacist before receiving Flucloxacillin Eberth.

- if you have kidney problems
- if you have liver problems
- if you are taking or will be taking paracetamol
- if you have ever had a skin rash or swelling of the face or neck when taking an antibiotic.
- if you are on a low sodium diet.
- if the skin of your newborn baby appears yellow (jaundice)
- if you have stomach pain and diarrhoea, which may contain blood and mucus
- if you are 50 years of age or older
- if you have any serious health conditions

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.

The use of flucloxacillin, especially in high doses, may reduce the potassium levels in the blood (hypokalemia). Your doctor may measure your potassium levels regularly during the therapy with higher doses of flucloxacillin.

Other medicines and Flucloxacillin Eberth

Tell your doctor or pharmacist if you are taking/ using, have recently taken/ used or might take/ use any other medicines, especially:

- Methotrexate (used to treat some autoimmune disorders) can reduce the elimination of flucloxacillin (increased risk of toxicity)
- Probenecid and sulfinpyrazone (used in the treatment of gout), phenylbutazone, oxyphenbutazone and indometacin (antirheumatic agents) and acetyl salicylic acid (an analgesic) as these may interfere with how the body removes flucloxacillin
- Voriconazole (used against fungal infections)
- Medicines to prevent blood clots (e.g. warfarin), as an altered (usually reduced) INR (International Normalised Ratio) has been described in rare cases in patients receiving warfarin and flucloxacillin concomitantly.

Other antibiotics such as chloramphenicol, erythromycin, and tetracyclines (used to treat some infections) as it may affect the action of flucloxacillin.

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 pharmacist for advice before taking this medicine.

Flucloxacillin Eberth should only be used by pregnant women if considered essential by the doctor. Flucloxacillin passes into breast milk, so ask your doctor for advice before you receive Flucloxacillin Eberth.

Driving and using machines

Flucloxacillin Eberth is not known to have any affect on your ability to drive or operate machinery.

Flucloxacillin Eberth contains sodium.

Each vial containing 1 g powder for solution for injection/infusion contains 2.2 mmol sodium (51 mg) (main component of cooking/table salt). This is equivalent to 2.55% of the recommended maximum daily dietary intake of sodium for an adult.

Each vial containing 2 g powder for solution for injection/infusion contains 4.4 mmol sodium (102 mg) (main component of cooking/table salt). This is equivalent to 5.1% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Flucloxacillin Eberth is given

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

Your doctor or healthcare professional will give you this medicine by injection into a muscle (intramuscular), injection into a vein (intravenous) or by infusion. Flucloxacillin Eberth should not be administered into the eye.

Adults and adolescents at and over 12 years

1000 mg – 4000 mg/day given in three to four divided doses.

For severe infections: up to 8000 mg daily can be given, administered in 4 infusions (over 20-30 minutes).

No single dose, by injection or infusion should exceed 2000 mg.

Maximum daily dose: 12 000 mg.

For infection of the heart (endocarditis): 2000 mg of flucloxacillin every 6 hours, increasing to 2000 mg every 4 hours in patients weighing >85 kg.

To prevent infections after an operation the usual dose is 2000 mg before the operation when you are given your anaesthetic. This is then followed by 2000 mg every 6 hours for 24 hours in cases of vascular or orthopaedic surgery and for 48 hours in cases of cardiac or coronary surgery.

Children under 12 years

In mild to moderate infections: 25-50 mg per kg body weight in 24 hours. This will be given in three or 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.

For infections of the heart (endocarditis): 200 mg/kg/24 hours of flucloxacillin in three to four divided doses.

No single dose, by injection or infusion should exceed 33 mg per kg body weight.

Premature infants, neonates, sucklings and infants

Flucloxacillin should be administered to premature infants and neonates only after strict risk-benefit assessment because of the possible triggering of kernicterus (rare brain damage).

Neonates and premature babies and infants generally receive 25 mg to 50 mg/kg/24 hours, divided into three to four equal doses. The daily dose may be increased to a maximum of 100 mg/kg/24 hours.

Patients with severe kidney problems

If you have kidney problems, you may be given a lower dose just twice or three times a day depending on your kidney function.

If you are given more Flucloxacillin Eberth than you should

As this medicine will normally be given to you by a healthcare professional or a doctor it is unlikely you will be given too much, but if you think you have been given too much Flucloxacillin Eberth tell your doctor or healthcare professional immediately. Signs may be nausea, vomiting and diarrhoea.

If you forget to receive Flucloxacillin Eberth

As this medicine will normally be given to you by a healthcare professional or a doctor it is unlikely you will miss a dose, but if you have any concerns discuss this with your doctor or healthcare professional.

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

4. Possible side effects

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

If you notice any of the following serious side effects, stop taking Flucloxacillin Eberth and contact a doctor immediately:

- Severe prolonged diarrhoea, which may have blood or mucus in it, accompanied with stomach pain and fever. This could be “pseudomembranous colitis”.
- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow (severe allergic reaction).
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be “Stevens-Johnson syndrome” or “toxic epidermal necrolysis”.

These effects are very rare, affecting up to 1 in 10,000 people.

Other side effects include:

Common (may affect up to 1 in 10 people)

- Minor gastrointestinal disturbances

Uncommon (may affect up to 1 in 100 people)

- Skin rash, itchy skin.
- Red or purple spots on the skin caused by bleeding underneath the skin

Very rare (may affect up to 1 in 10000 people)

- Abnormal decrease in some types of white blood cells in your blood (neutropenia) which can make you more likely to get infections
- Unusual bleeding or bruising caused by a reduction in the number of platelets in the blood (thrombocytopenia)
- Abnormal increase in a certain type of white blood cells in your blood (eosinophilia). Symptoms include weight loss, night sweats and fever
- Abnormal breakdown of red blood cells (haemolytic anaemia). Symptoms include tiredness, paleness, yellowing of skin, weakness, dizziness, shortness of breath and fast heart beat.
- Convulsion (fits) with very high doses of flucloxacillin in patients with kidney failure
- Skin rash, which may blister, and look like small targets with central dark spots surrounded by a paler area, with dark ring around the edge (Erythema multiforme)
- Inflammation of the liver (hepatitis), jaundice (yellowing of the skin and whites of eye)
- Changes to the results of liver function tests
- Joint pain and muscular pain
- Kidney problems
- Fever
- 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, generally in the presence of risk factors (see section 2).

Not known (cannot be determined from the available data)

- Serious skin reactions. A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). Contact a doctor immediately if you get any of these symptoms.
- Inflammation of blood vessels (phlebitis).
- 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 healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flucloxacillin Eberth

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 label and carton after EXP. The expiry date refers to the last day of that month.

Flucloxacillin Eberth does not require any special storage conditions.

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 Eberth contains

The active substance is flucloxacillin.

Each vial contains 1000 mg flucloxacillin in the form of flucloxacillin sodium monohydrate.

Each vial contains 2000 mg flucloxacillin in the form of flucloxacillin sodium monohydrate.

What Flucloxacillin Eberth looks like and contents of the pack

The medicinal product is packed in clear glass vials type III, sealed with chlorobutyl rubber stoppers type I and coloured flip-off aluminum caps.

Flucloxacillin Eberth 1000 mg powder for solution for injection/infusion:

The vial size has a nominal capacity of 20 ml.

Pack sizes: 1 and 10 vials

Flucloxacillin Eberth 2000 mg powder for solution for injection/infusion:

The vial size has a nominal capacity of 50 ml.

Pack sizes: 1 and 10 vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Vergunninghouder:

Dr. Friedrich Eberth Arzneimittel GmbH

Am Bahnhof 2

92289 Ursensollen

Duitsland

Fabrikant:

Medochemie Ltd

Agios Athanassios Industrial Area, Iapetou 48, Limassol, 4101, Cyprus

In het register ingeschreven onder:

Flucloxacilline Eberth 1 g poeder voor oplossing voor injectie/infusie

RVG 134164

Flucloxacilline Eberth 2 g poeder voor oplossing voor injectie/infusie

RVG 134165

This medicine is authorised in the Member States of the European Economic Area under the following names:

Netherlands	Flucloxacilline Eberth 1g en 2g poeder voor oplossing voor injectie/infusie
Germany	Flucloxacillin Eberth 1000 mg und 2000 mg Pulver zur Herstellung einer Injektions-/Infusionslösung

Deze bijsluiter is voor het laatst goedgekeurd in juli 2026.

The following information is intended for healthcare professionals only:

Preparation of the solution

Intramuscular

Add 4 ml of diluent to a 1000 mg vial, as shown in below table.

Add 4 ml of diluent to a 2000 mg vial, as shown in below table.

Intravenous

Flucloxacillin Eberth can be added to the following diluents:

- Water for injections,
- Sodium chloride 9 mg/mL (0.9%) solution,
- Glucose 50 mg/mL (5%) solution,
- Sodium chloride 1.8 mg/mL (0.18%) with Glucose 40 mg/mL (4%) solution

For intravenous injection:

Dissolve 1000 mg in 20 ml of diluent.

Dissolve 2000 mg in 40 ml of diluent.

Administer by slow intravenous injection.

For intravenous infusion:

Flucloxacillin Eberth can also be added slowly through infusion fluids or injected, appropriately diluted over the concentration range of 5 mg/ml to 40 mg/ml using the specified diluents in the dropper tube.

Route	Infusion fluids/Solvents	
	Volume	Type
i.m. Flucloxacillin Eberth 1000 mg Flucloxacillin Eberth 2000 mg	4 ml 4 ml	Water for injections Lidocaine 10 mg/ml (1%) solution
i.v. Flucloxacillin Eberth 1000 mg Flucloxacillin Eberth 2000 mg	20 ml 40 ml	Water for injections Sodium chloride 9 mg/ml (0.9%) solution Glucose 50 mg/ml (5%) solution Sodium chloride 1.8 mg/ml (0.18%) + Glucose 40 mg/mL (4%) solution
perfusion i.v. Flucloxacillin Eberth 1000 mg Flucloxacillin Eberth 2000 mg	Volume corresponding to a concentration of 5mg/ml to 40mg/ml	Water for injections Sodium chloride 9 mg/ml (0.9%) solution Glucose 50 mg/mL (5%) solution Sodium chloride 1.8 (0.18%) + Glucose 40 mg/ml (4%) solution Hartmann solution
Do not administer parenterally more than 2 g (adults) or more than 33 mg/kg (children) at one time. From a microbiological point of view, the product should be used immediately.		

Solution for intramuscular injection:

Chemical and physical in-use stability has been demonstrated for 2 hours in the refrigerator (2–8°C).

Solution for intravenous injection:

Chemical and physical in-use stability been demonstrated for 4 hours at room temperature (25°C) and for 24 hours in the refrigerator (2–8°C).

Solution for intravenous infusion:

Chemical and physical in-use stability has been demonstrated for 2 hours at room temperature (25°C) and for 24 hours in the refrigerator (2–8°C).

Chemical and physical in-use stability has been demonstrated for 2 hours at 2-8°C when diluted to a final concentration of 5 mg/ml to 40 mg/ml with Hartmann solution.

From a microbiological point of view, unless the method of reconstitution/dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of user.

Appearance of the solution: clear, colourless or pale yellow, practically particle-free solution. Only clear solutions practically free from particles should be used.

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

Incompatibilities

Flucloxacillin should not be mixed with blood products or other protein fluids (e.g. protein hydrolysates) or with intravenous lipid emulsions.

If flucloxacillin is prescribed concomitantly with an aminoglycoside, the two antibiotics should not be mixed in the same syringe, intravenous fluid container or the given set; precipitation may occur.