Package leaflet: Information for the patient

Flucloxacillin 500 mg
powder for solution for injection/infusion

Flucloxacillin 1000 mg
powder for solution for injection/infusion

Flucloxacillin 2000 mg
powder for solution for injection/infusion

flucloxacillin

Read all of this leaflet carefully before you are given 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.

What is in this leaflet

1. What Flucloxacillin is and what it is used for

Flucloxacillin 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 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 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

Flucloxacillin must not be given
- if you are allergic to flucloxacillin or other betalactam antibiotics (e.g. penicillins, cephalosporins), or any of the other ingredients of this medicine (listed in section 6)
- 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:

- 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 (hypokalaemia). Your doctor may measure your potassium levels regularly during the therapy with higher doses of flucloxacillin.

Other medicines and Flucloxacillin
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
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)

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

Pregnancy and breast-feeding
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 receiving this medicine.

Flucloxacillin 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.

Driving and using machines
Flucloxacillin is not known to have any affect on your ability to drive or operate machinery.

Flucloxacillin contains sodium
Flucloxacillin 500 mg powder for solution for injection/infusion contains approximately 25.5 mg sodium per vial (10 ml), equivalent to 1.28 % of the WHO recommended maximum daily intake of 2 g sodium for an adult. To be taken into consideration by patients on a controlled sodium diet.

Flucloxacillin 1000 mg powder for solution for injection/infusion contains approximately 51 mg sodium per vial (20 ml), equivalent to 2.55 % of the WHO recommended maximum daily intake of 2 g sodium for an adult. To be taken into consideration by patients on a controlled sodium diet.

Flucloxacillin 2000 mg powder for solution for injection/infusion contains approximately 102 mg sodium per vial (50 ml), equivalent to 5.1 % of the WHO recommended maximum daily intake of 2 g sodium for an adult. To be taken into consideration by patients on a controlled sodium diet.

3. How Flucloxacillin 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 nurse will give you this medicine by injection into a muscle (intramuscular) or injection into a vein (intravenous). Flucloxacillin should not be administered into the eye.

Flucloxacillin 500 mg powder for solution for injection/infusion can also be given to you by injection into a joint (intraarticular) or injection into the lining of the lung (intrapleural).
Injection into a muscle (intramuscular) or injection into a vein (intravenous)
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.

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.

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.

Flucloxacillin 500 mg powder for solution for injection/infusion may be administered by other routes, together with systemic therapy:
- 500 mg by injection into the lining of the lung (intrapleural) and injection into a joint (intraarticular).

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 forget to receive 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 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 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.

The following information is intended for healthcare professionals only:

For single use only. Discard any unused solution.

Preparation of solution
Flucloxacillin 500 mg may be added to the following infusion fluids:
water for injections, sodium chloride 9 mg/ml (0.9%), glucose 50 mg/ml (5%) and lidocaine hydrochloride 5 mg/ml (0.5%)

Flucloxacillin 1000 mg and Flucloxacillin 2000 mg may be added to the following infusion fluids:
water for injections, sodium chloride 9 mg/ml (0.9%), glucose 50 mg/ml (5%), lidocaine hydrochloride 5 mg/ml (0.5%) and lidocaine hydrochloride 10 mg/ml (1%).

Instruction for reconstitution

Reconstituted product:

Route of Administration	Strengths [mg]	Infusion fluids/ solvents	Volume to be added [ml]	Approximate available volume per flask (ml)	Approximate flucloxacillin concentration per flask (mg/ml)
intramuscular	250	Water for injections	1.5	1.6	155
		Sodium chloride 0.9% / Lidocaine hydrochloride 0.5%	1.5	1.7	145
	500	Water for injections	2	2.2	225
		Sodium chloride 0.9% / Lidocaine hydrochloride 0.5%	2	2.3	215
	1000	Water for injections / Sodium chloride 0.9%	3	3.6	280
		Lidocaine hydrochloride 0.5% / Lidocaine hydrochloride 1.0%	3	3.7	270
	2000	Water for injections	4	5.2	385
		Sodium chloride 0.9%	4	5.3	375
		Lidocaine hydrochloride 0.5%	4	5.4	370
		Lidocaine hydrochloride 1.0%	4	5.2	385
intravenous	250	Water for injections / Sodium chloride 0.9% / Glucose 5%	5	5.1	50
	500	Water for injections / Sodium chloride 0.9% / Glucose 5%	10	10.3	50
	1000	Water for injections	20	21	45
		Sodium chloride 0.9% / Glucose 5%	20	20.5	50
	2000	Water for injections / Sodium chloride 0.9% / Glucose 5%	40	41	50

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 10,000 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). Symtoms 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 (frequency cannot be estimated 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 nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance
Website: www.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.

Use immediately after opening and only undamaged containers. For single use only.
Do not use if the vial is damaged or broken.
Unopened product: This medicine does not require any special storage conditions.
Reconstituted solution:
When the product is reconstituted or further diluted with Water for Injections, Sodium Chloride 0.9%, Glucose 5%, Lidocaine hydrochloride 0.5% or Lidocaine hydrochloride 1%, the chemical and physical in-use stability of reconstituted product has been demonstrated for 2 hours at 20-25ºC and for 24 hours at 2-8ºC.
From a microbiological point of view, unless the method of opening/ reconstitution/ dilution precludes the risk of microbial contamination, 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 not be longer than the times stated above for the chemical and physical in-use stability.
Do not use this medicine if there are any visible signs of deterioration.
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.

For single use only. Discard any unused solution.

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 to protect the environment.

6. Contents of the pack and other information

What Flucloxacillin contains
The active substance is flucloxacillin.
Flucloxacillin 500 mg powder for solution for injection/infusion
Each vial contains 500 mg flucloxacillin (as flucloxacillin sodium).
Flucloxacillin 1000 mg powder for solution for injection/infusion
Each vial contains 1000 mg flucloxacillin (as flucloxacillin sodium).
Flucloxacillin 2000 mg powder for solution for injection/infusion
Each vial contains 2000 mg flucloxacillin (as flucloxacillin sodium).
The other ingredients: none

What Flucloxacillin looks like and contents of the pack
Flucloxacillin is a fine white or almost white, hygroscopic, crystalline sterile powder for solution for injection/infusion.

Flucloxacillin 500 mg: 10 ml Type II glass vial closed with halobutyl stoppers and green aluminium/plastic flip-off caps.

Packs of 10 vials and 50 vials.
Not all pack sizes may be marketed.

Flucloxacillin 1000 mg: 20 ml Type II glass vial closed with halobutyl stoppers and blue aluminium/plastic flip-off caps.

Packs of 10 vials and 50 vials.
Not all pack sizes may be marketed.

Flucloxacillin 2000 mg: 50 ml Type II glass vial closed with halobutyl stoppers and red aluminium/plastic flip-off caps.

Packs of 10 vials and 50 vials.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Fresenius Kabi Deutschland GmbH
Else-Kröner-Straße 1,
61352 Bad Homburg v.d.Höhe
Germany

Manufacturer
Labesfal – Laboratórios Almiro, S.A.,
Fresenius Kabi Group
3465-157 Santiago de Besteiros, Portugal

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member State	Name of the medicinal product
Austria	Flucloxacillin Kabi 250 mg Pulver zur Herstellung einer Injektions-/Infusionslösung
	Flucloxacillin Kabi 500 mg Pulver zur Herstellung einer Injektions-/ Infusionslösung
	Flucloxacillin Kabi 1000 mg Pulver zur Herstellung einer Injektions-/ Infusionslösung
	Flucloxacillin Kabi 2000 mg Pulver zur Herstellung einer Injektions-/ Infusionslösung
Belgium	Flucloxacilline Fresenius Kabi 250 mg poeder voor oplossing voor injectie/infusie
	Flucloxacilline Fresenius Kabi 500 mg poeder voor oplossing voor injectie/infusie
	Flucloxacilline Fresenius Kabi 1000 mg poeder voor oplossing voor injectie/infusie
	Flucloxacilline Fresenius Kabi 2000 mg poeder voor oplossing voor injectie/infusie
Czech Republic	Flucloxacillin Fresenius Kabi
Germany	Flucloxacillin Kabi 250 mg Pulver zur Herstellung einer Injektions-/Infusionslösung
	Flucloxacillin Kabi 500 mg Pulver zur Herstellung einer Injektions-/ Infusionslösung
	Flucloxacillin Kabi 1000 mg Pulver zur Herstellung einer Injektions-/ Infusionslösung
	Flucloxacillin Kabi 2000 mg Pulver zur Herstellung einer Injektions-/ Infusionslösung
Ireland	Flucloxacillin 500mg powder for solution for injection/infusion
	Flucloxacillin 1000mg powder for solution for injection/infusion
	Flucloxacillin 2000mg powder for solution for injection/infusion
Netherlands	Flucloxacilline Kabi 250 mg poeder voor oplossing voor injectie/infusie
	Flucloxacilline Kabi 500 mg poeder voor oplossing voor injectie/infusie
	Flucloxacilline Kabi 1000 mg poeder voor oplossing voor injectie/infusie
	Flucloxacilline Kabi 2000 mg poeder voor oplossing voor injectie/infusie
Portugal	Flucloxacilina Kabi
Slovenia	Flukloksacilin Kabi 250 mg prašek za raztopino za injiciranje/infundiranje
	Flukloksacilin Kabi 500 mg prašek za raztopino za injiciranje/infundiranje
	Flukloksacilin Kabi 1000 mg prašek za raztopino za injiciranje/infundiranje
	Flukloksacilin Kabi 2000 mg prašek za raztopino za injiciranje/infundiranje
Slovakia	Flucloxacillin Fresenius Kabi 1 g
	Flucloxacillin Fresenius Kabi 2 g

This leaflet was last revised in April 2023.

FRESENIUS KABI

Route of Administration	Strengths [mg]	Infusion fluids/ solvents	Volume to be added [ml]	Approximate available volume per flask (ml)	Approximate flucloxacillin concentration per flask (mg/ml)
intrapleural	250	Water for injections	5	5.1	50
		Sodium chloride 0.9%			
		Water for injections	10	10.2	25
		Sodium chloride 0.9%			
	500	Water for injections	5	5.4	95
		Sodium chloride 0.9%			
		Water for injections	10	10.3	50
		Sodium chloride 0.9%			
intraarticular	250	Water for Injections	5	5.1	50
		Sodium chloride 0.9%			
	500	Water for Injections	5	5.4	95
		Sodium chloride 0.9%			

Reconstitution with water for injections, sodium chloride 9 mg/ml (0.9%), glucose 5 mg/ml (5%), lidocaine hydrochloride 5 mg/ml (0.5%) and lidocaine hydrochloride 1 mg/ml (1%):
Chemical and physical in-use stability of reconstituted or further diluted product has been demonstrated for 2 hours at 20-25 ºC and for 24 hours at 2-8 ºC.

From a microbiological point of view, unless the method of opening/ reconstitution/ dilution precludes the risk of microbial contamination, 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 not be longer than the times stated above for the chemical and physical in-use stability.

When the product is reconstituted with Water for Injections, Sodium Chloride 0.9%, Glucose 5%, Lidocaine hydrochloride 0.5% or Lidocaine hydrochloride 1%, the chemical and physical in-use stability of reconstituted product has been demonstrated for 2 hours at 20-25ºC and for 24 hours at 2-8ºC. 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 8ºC (in a refrigerator), unless reconstitution and dilution has taken place in controlled and validated aseptic conditions.

In case precipitations are seen after the reconstitution, shake well before use.

Incompatibilities
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 same syringe, intravenous fluid container or giving set; precipitation may occur.

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