

Package leaflet: information for the user

Flucloxacillin Aurobindo 250 mg, capsules
Flucloxacillin Aurobindo 500 mg, capsules
flucloxacillin

Read the entire 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.

Do you have any questions? Please contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed for you only. It may harm others, even if their symptoms are the same as yours.

Do you experience a lot of discomfort from one of the side effects listed in section 4?

Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.

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1. What is Flucloxacillin Aurobindo and what is this medicine used for?

Flucloxacillin Aurobindo belongs to a group of medicines called antibiotics. Flucloxacillin ensures that certain types of bacteria are rendered harmless.

The doctor prescribes you Flucloxacillin Aurobindo for the treatment of certain mild to moderately severe infections caused by bacteria sensitive to flucloxacillin.

Upper respiratory tract infections such as sore throat, inflamed tonsils, or cold.

Lower respiratory tract infections such as pneumonia.

Infections of the skin and soft tissues such as impetigo and abscess.

2. When should you not use this medicine or be extra careful?

When should you not use this medicine?

You are allergic to soy or any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.

You should not use flucloxacillin if you are hypersensitive to soy, penicillin-type antibiotics, or other antibiotics such as cephalosporins. Hypersensitivity may occur if you suddenly experience shortness of breath, a tight feeling in the chest, palpitations, swollen eyelids or lips, rash, or hives after taking flucloxacillin. Do not use, if you recognize the above symptoms, flucloxacillin until you have consulted your doctor.

Flucloxacillin should not be used by patients with jaundice caused by flucloxacillin or with liver disorders in their medical history.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

With prolonged use of flucloxacillin, your doctor will regularly monitor your liver and kidney function and, if necessary, reduce the dosage or extend the dosing interval. In patients over 50 years of age and in patients with a serious underlying disease, the doctor should be extra cautious due to the possible occurrence of liver function disorders.

In patients with a serious renal impairment the doctor will reduce the dosage or extend the dosing interval.

When used in newborns who are jaundiced, your doctor will be extra cautious and reduce the dosage if necessary.

In newborns and children under 6 months, your doctor will reduce the dosage if necessary because their kidneys remove the active substance from the body more slowly.

If you use flucloxacillin for an extended period (or multiple courses in succession), there is a possibility that you may experience bacteria that are not sensitive to flucloxacillin. Consult in that case your doctor.

If colitis occurs, the treatment with flucloxacillin should be stopped, and you should contact a doctor immediately (see also "Possible side effects").

If you are using or going to use paracetamol.

Use of flucloxacillin, especially in high doses, can lower the potassium level in the blood (hypokalemia). It is possible that your doctor will regularly check your potassium levels during treatment with higher doses of flucloxacillin.

There is a risk of abnormalities in the blood and fluid (high anion gap metabolic acidosis), which occur when there is an increased acidity of the plasma, when flucloxacillin is used simultaneously with paracetamol, particularly in certain at-risk patients, such as those with severe renal insufficiency, sepsis, or malnutrition, especially if the maximum daily doses are used. Are you using any other medications?

Are you using any other medications besides Flucloxacillin?

Are you using any other medications besides Flucloxacillin? Aurobindo any other medicines, have you done that recently or are you going to do this soon? Tell that then your doctor or pharmacist.

Flucloxacillin should not be administered simultaneously with bacteriostatic medicines (medicines that inhibit the growth of bacteria) such as tetracyclines, macrolides, and chloramphenicol.

Simultaneous use with aminoglycosides (medicines that kill bacteria) is possible, but flucloxacillin and aminoglycosides can enhance each other's effects.

A number of medicines can inhibit the excretion of penicillin-like medicines via urine (phenylbutazone, oxyphenbutazone, and to a lesser extent acetylsalicylic acid (pain-relieving medicines), indomethacin (medicine against rheumatism and gout)) resulting in a higher concentration of flucloxacillin in the body and a longer time before flucloxacillin is excreted.

Because flucloxacillin can affect the intestinal flora, the reliability of oral contraceptives (the "pill") is reduced.

Voriconazole (medicine against fungal infections).

What should you pay attention to with food and drink?

Flucloxacillin Aurobindo should be taken on an empty stomach, for example 1 hour before or 2 hours after a meal.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

There is currently not enough data available on the use of flucloxacillin during pregnancy. If you are pregnant and want to use flucloxacillin, you should first consult your doctor. Breastfeeding can be given during the use of flucloxacillin.

Driving ability and the use of machines

There is no known data on the effect of this product on driving ability. However, an adverse effect is unlikely.

Flucloxacillin Auro contains soy lecithin

Do not use this medicine if you are allergic to peanuts or soy.

Flucloxacillin Auro contains sodium

250 mg capsules: this medicine contains less than 1 mmol sodium (23 mg) per capsule, which means it is essentially 'sodium-free'.

500 mg capsules: this medicine contains 25.9 mg sodium (a major component of cooking/table salt) per capsule. This corresponds to 1.3% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Take your flucloxacillin hard capsule at least 1 hour before or 2 hours after a meal. To reduce the risk of pain in your esophagus (the tube that connects your mouth to your stomach), you should swallow the capsules with a large glass of water (250 ml) and not lie down immediately after taking your capsules.

The usual dosage is as follows:

3 times a day (every 8 hours)

*For adults and children over 12 years, it is recommended to use Flucloxacillin Aurobindo capsules of 250 mg or 500 mg. For children between 6 and 12 years, it is usually also recommended to use Flucloxacillin Aurobindo capsules.

Use in adults and children over 12 years*

3 times a day 500 mg

Use in children aged 6-12 years*

3 times daily 250 mg

**For children younger than 6 years, it is recommended to use flucloxacillin oral suspension 125mg/5ml. The dosage is as follows:

Use in children aged 2-6 years**

3 times daily 250 mg (= 3 times daily 10 ml suspension).

Use in children up to 2 years**

3 times daily 125 mg (= 3 times daily 5 ml suspension).

Dosage for severe infections (adults and children) In severe infections, the dose can be doubled.

Use in reduced kidney function

If your kidneys are not working well, your doctor will be extra careful when you use flucloxacillin. Sometimes the doctor may adjust the flucloxacillin dosage or dosing interval. For children under 12 years, your doctor will also adjust the dosage if they have severe kidney problems.

Have you used too much of this medicine?

If you have taken more flucloxacillin than your doctor has prescribed, it is advisable to contact your doctor immediately. Overdose can lead to gastrointestinal symptoms (nausea, vomiting, and diarrhea) and a disturbance of fluid and electrolyte balance. The treatment for overdose consists of maintaining the fluid and electrolyte balance.

Have you forgotten to use this medicine?

Take the missed dose as soon as you remember, unless it is almost time for the next dose. The next dose should then be taken at the prescribed time. However, never take a double dose to make up for the missed dose.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can also have side effects. Not everyone experiences them.

The following frequencies are used for the occurrence of side effects:

Very common (occur in more than 1 in 10 users)

Common (occurs in less than 1 in 10 users)

Uncommon (occurs in less than 1 in 100 users)

Rare (occurs in less than 1 in 1,000 users)

Very rare (occurs in less than 1 in 10,000 users)

Not known (frequency cannot be estimated from the available data)

Blood and lymphatic system disorders

Very rare: blood disorder (lack of white blood cells) associated with increased susceptibility to infections (neutropenia) and blood disorder (lack of platelets) associated with bruising and

bleeding tendency (thrombocytopenia). This disappears if the treatment is stopped.
Eosinophilia (increase of eosinophilic cells in the blood). Anemia due to excessive breakdown of blood (hemolytic anemia).

Immune system disorders

Very rare: shock (severe drop in blood pressure, paleness, restlessness, weak rapid pulse, clammy skin, reduced consciousness) due to a sudden severe dilation of blood vessels as a result of severe hypersensitivity to certain substances (anaphylactic shock). Sudden fluid accumulation in the skin and mucous membranes (e.g., throat or tongue), breathing difficulties and/or itching and skin rash, often as an allergic reaction (angioneurotic edema). If these reactions occur, you should contact a doctor immediately.

Gastrointestinal disorders

Uncommon: minor disturbances of the gastrointestinal tract.
Very rare: inflammation of the colon (pseudomembranous colitis).

Liver or bile disorders

Very rare: liver inflammation associated with jaundice (yellowing of the skin or eyes) (hepatitis) and jaundice that occurs because bile and bile components cannot reach the intestine (cholestatic jaundice). Both can occur up to 2 months after stopping the treatment. In some cases, the course can be prolonged and last several months. Very rarely, a fatal outcome has been reported, almost always in patients over 50 years old or in patients with a serious underlying disease.

Disorders of the skin or subcutaneous tissue

Sometimes: rash, skin rash with severe itching and formation of bumps (urticaria) and bruising in the skin or mucous membranes (purpura).

Very rarely: skin rash with red (moist) irregular spots (erythema multiforme). Severe hypersensitivity reaction with (high) fever, red spots on the skin, joint pain and/or eye inflammation (Stevens-Johnson syndrome). Severe, sudden (hypersensitivity) exanthematous

Unknown: severe skin reactions. A red, scaly rash with bumps under the skin and blisters (exanthematous pustulose) Very rarely: joint pain and muscle pain. These sometimes develop only 48 hours after the start of treatment.

Disorders of the kidneys and urinary tract

Very rarely: kidney inflammation (interstitial nephritis). This disappears

Disorders of the kidneys and urinary tract

the treatment is stopped. General: Very rarely: fever that sometimes occurs only 48 hours after the start of treatment.

General:

Very rarely: fever that sometimes occurs only 48 hours after the start of treatment.

Very rare: very rare cases of blood and fluid abnormalities (high anion gap metabolic acidosis), which occur when there is an increased acidity of the plasma, when flucloxacillin is used simultaneously with paracetamol, usually when risk factors are present (see section 2).

Unknown: low potassium level in the blood (hypokalemia), which can cause muscle weakness, cramps, or an irregular heartbeat. Pain in the esophagus (the tube that connects the mouth to the stomach) and other related complaints, such as difficulty swallowing, heartburn, throat irritation, or chest pain.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb (www.lareb.nl). By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Store below 25°C in the original packaging to protect from moisture.

Do not use this medicine after the expiry date. You can find this on the packaging after "Exp.:". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

Flucloxacillin Aurobindo 250 and 500 mg capsules contain the active substance flucloxacillin sodium monohydrate, corresponding to 250 and 500 mg flucloxacillin per capsule, respectively.

The other substances in this medicine are magnesium stearate and silicon dioxide.

Additionally, the capsule shell contains: gelatin, red iron oxide (E 172), yellow iron oxide (E 172), titanium dioxide (E 171), black iron oxide (E 172), and white ink, which contains, among other things, shellac, lecithin, dimethicone and titanium dioxide (E 171).

What does Flucloxacillin Aurobindo look like and what is in a package?

250 mg: hard gelatin capsule filled with white powder, brown body and black cap, "FLUCLOX" in white letters on the cap, "250" in white letters on the body.

500 mg: hard gelatin capsule filled with white powder, brown body and black cap, "FLUCLOX" in white letters on the cap, "500" in white letters on the body.

The capsules are packed per 20 capsules in blister packs or per 20 or 100 capsules in a bottle. It is possible that not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturers Marketing authorization holder:
Aurobindo Pharma B.V., Baarnsche Dijk 1, 3741 LN Baarn

Manufacturers:

Aurobindo Pharma B.V., Baarnsche Dijk 1, 3741 LN Baarn

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland

Registered in the register

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This leaflet was last approved in August 2023

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