

Package leaflet: Information for the user

Flucloxacillin Orion 500 mg film-coated tablets Flucloxacillin Orion 750 mg film-coated tablets Flucloxacillin Orion 1 g film-coated tablets

flucloxacillin

Read all of this leaflet carefully before you start taking 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

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2. What you need to know before you take Flucloxacillin Orion
3. How to take Flucloxacillin Orion
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1. What Flucloxacillin Orion is and what it is used for

The active substance in Flucloxacillin Orion is flucloxacillin. Flucloxacillin is a penicillin (antibiotic), which prevents bacteria from building up a normal cell wall. Without functioning cell walls, bacteria die quickly. Flucloxacillin Orion is stable against an enzyme (lactamase), which is capable of breaking down ordinary penicillin.

Flucloxacillin Orion is used for:

- infections of the skin and soft tissues
- infections of the joints, bone and lungs (e.g. pneumonia, chronic bronchitis).

2. What you need to know before you take Flucloxacillin Orion

Do not take Flucloxacillin Orion

- if you are allergic to flucloxacillin, penicillin, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Flucloxacillin Orion if you:

- are allergic to cephalosporin (antibiotics)
- are elderly
- have a liver disease
- receive flucloxacillin for a long period
- are taking or will be taking paracetamol.

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.

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, 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.

Other medicines and Flucloxacillin Orion

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is important as certain medicines may influence or be influenced by the treatment with Flucloxacillin Orion.

These include for example:

- methotrexate (a medicine against tumours and disorders of the immune system)
- probenecid (used to treat gout)
- warfarin (a medicine to prevent blood clotting)
- voriconazole (used against fungal infections)
- paracetamol (used to treat pain and fever)
- immunosuppressants (eg tacrolimus, everolimus and ciclosporin).

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 for advice before taking this medicine.

There are no known risks in connection with use during pregnancy. Flucloxacillin passes into the mother's milk but is not likely to affect infants who are breast-fed. Your doctor will assess whether you can take Flucloxacillin Orion during pregnancy or breast-feeding.

Driving and using machines

This medicine has no or negligible influence on the ability to drive and use machines.

Excipients

500 mg tablet contains 28 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1.4% of the recommended maximum daily dietary intake of sodium for an adult.

750 mg tablet contains 42 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 2.1% of the recommended maximum daily dietary intake of sodium for an adult.

1 g tablet contains 56 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 2.8% of the recommended maximum daily dietary intake of sodium for an adult.

To be taken into consideration by patients on a controlled sodium diet.

3. How to take Flucloxacillin Orion

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The doctor determines the dose so that it is suitable for you.

Take the tablets between meals to get the best effect of Flucloxacillin Orion.

Take your flucloxacillin tablets at least 1 hour before or 2 hours after meals.

To reduce the risk of pain in your oesophagus (the tube that connects your mouth with your stomach) swallow the tablets with a full glass of water (250 ml) and do not lie down immediately after taking your tablets.

If you take more Flucloxacillin Orion than you should

If you have taken too much of the medicine or if, for example, a child has taken the medicine by mistake, contact your doctor, hospital *<to be completed nationally>* for an assessment of the risk and advice.

If you forget to take Flucloxacillin Orion

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking Flucloxacillin Orion

Even if you feel better after a few days, it is important that you complete the whole course of treatment with Flucloxacillin Orion according to the prescription. Otherwise, some bacteria may survive, grow in numbers and cause a new outbreak of the infection.

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.

Stop taking Flucloxacillin Orion and contact a doctor immediately if you get any of the following symptoms of rare side effects (may affect up to 1 in 1 000 people):

- Symptoms of severe allergic reaction such as swelling of the face, tongue or throat, difficulties in swallowing, nettle rash and breathing difficulties
- Severe diarrhoea, usually with blood or mucous, stomach pain, fever (pseudomembranous colitis)
- Reduction in the number of white blood cells (agranulocytosis or neutropenia) causing fever and serious weakening of your general condition or fever with local infection symptoms such as sore throat or mouth or urinary problems
- Signs of liver injury or disease such as darker urine or paler stools, yellowing of the skin or the white of the eyes (jaundice)
- Sudden onset of severe rash which may include blistering or peeling of the skin and mucous membranes (erythema multiforme, Stevens-Johnson syndrome or toxic epidermal necrolysis). Severe reactions may also be associated with fever, ulcers on the surface of the eyes, and joint pains.

Common (may affect up to 1 in 10 people):

- Nausea or diarrhoea
- Skin rashes.

Uncommon (may affect up to 1 in 100 people):

- Large number of a certain type of white blood cells (eosinophilia)
- Nettle rash.

Very rare (may affect up to 1 in 10 000 people):

- Itching.
- Very rare 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 (frequency cannot be estimated from the available data):

- Dizziness
- Abdominal pain, vomiting
- 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
- Low potassium levels in the blood (hypokalaemia), which can cause muscle weakness, twitching or abnormal heart rhythm
- Pain in oesophagus (the tube that connects mouth with stomach) and other related symptoms, such as difficulties in swallowing, heartburn, throat irritation or chest pain.

Itching in the genitals may be caused by fungal overgrowth. White coating in the mouth, especially on the tongue may also be caused by a fungal infection.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flucloxacillin Orion

This medicinal product does not require any special storage conditions.

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

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 Orion contains

- The active substance is flucloxacillin. Each tablet contains flucloxacillin sodium monohydrate equivalent to 500 mg, 750 mg or 1 g flucloxacillin.
- The other ingredients are:
Tablet core: magnesium stearate, povidone, croscarmellose sodium, microcrystalline cellulose
Film-coating: titanium dioxide, macrogols, light liquid paraffin, hypromellose.

What Flucloxacillin Orion looks like and contents of the pack

Film-coated tablet (tablet).

500 mg: White to off-white, capsule shaped, film-coated biconvex tablets debossed with 'Y' on one side and '05' with score line between '0' and '5' on the other side, 17.4 x 8.1 mm. The tablet can be divided into equal doses.

750 mg: White to off - white, capsule shaped, film - coated biconvex tablets debossed with 'Y' on one side and '06' with score line between '0' and '6' on the other side, 20.4 x 8.4 mm. The tablet can be divided into equal doses.

1 g: White to off-white, elliptical shaped, film-coated biconvex tablets debossed with 'T' on one side and '63' with score line between '6' and '3' on the other side, 9.8 x 21.3 mm. The tablet can be divided into equal doses.

Pack sizes:

500 mg: 30, 50 and 100 tablets in plastic container.
750 mg: 20, 30, 50 and 100 tablets in plastic container.
1 g: 21, 30, 50 and 75 tablets in plastic container.
Each container contains desiccant.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer

Orion Corporation Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

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