

APO-Flucloxacillin

Flucloxacillin sodium

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about flucloxacillin. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What this medicine is used for

Flucloxacillin is used to treat infections in different parts of the body caused by bacteria. It belongs to a group of medicines called penicillins.

How it works

Flucloxacillin is an antibiotic that works by killing the bacteria that are causing your infection.

Flucloxacillin will not work against infections caused by viruses, such as colds or flu.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

There is not enough information to recommend the use of this medicine for children under the age of 2 years

Before you take this medicine

WARNING: Flucloxacillin can cause severe liver damage, particularly in older patients and those who take it for more than 14 days.

When you must not take it

Do not take this medicine if you are allergic to:

- flucloxacillin
- penicillin antibiotics
- cephalosporin antibiotics
- beta-lactam antibiotics including imipenem and aztreonam
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you have had a reaction affecting your liver while you were taking flucloxacillin or another penicillin antibiotic.

Examples of liver reactions include hepatitis and jaundice (yellowing of the eyes or skin).

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Do not use this medicine in your eyes.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver problems or jaundice (yellowing of the skin or eyes)
- kidney problems
- asthma, hayfever, eczema or other allergic conditions.

Tell your doctor if you are pregnant or you plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

The active ingredient Flucloxacillin passes into breast milk and there is a possibility that your baby may be affected.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor and pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you are taking this medicine in combination with paracetamol, particularly if you have impaired kidney function.

Some medicines and flucloxacillin may interfere with each other. This includes:

- probenecid, a medicine commonly used to treat gout
- some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with flucloxacillin. Talk to your doctor about the need for additional contraception while taking flucloxacillin.

These medicines may be affected by this medicine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid whilst taking this medicine.

Other medicines not listed above may also interact with flucloxacillin.

How to take this medicine

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

For most infections, the usual dose for adults is 250 mg every 6 hours.

For children 2-10 years: half adult dose.

How to take it

Swallow the capsules whole with a full glass of water.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Take flucloxacillin on an empty stomach, for example, half to one hour before meals and at bedtime.

Food can interfere with the absorption of flucloxacillin.

How long to take it for

Continue taking this medicine until you finish the pack, or for as long as your doctor tells you.

Do not stop taking this medicine, even if you feel better after a few days, unless advised by your doctor.

Your infection may not clear completely if you stop taking your medicine too soon.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much flucloxacillin, you may get diarrhoea and nausea.

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medication.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may occasionally do tests (such as liver function tests) to make sure the medicine is working and to prevent side effects.

If your symptoms do not improve within a few days, or if they become worse, tell your doctor.

If you develop jaundice (yellowing of the eyes or skin), tell your doctor immediately. Do this

even if it occurs several weeks after you have stopped taking flucloxacillin.

Jaundice may mean that you have a serious condition affecting your liver. You may need urgent medical care.

If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after you have stopped taking flucloxacillin.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without checking with your doctor.

If you get a sore, white mouth or tongue while taking or soon after stopping flucloxacillin, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes, the use of flucloxacillin allows fungi to grow and the above symptoms to occur. Flucloxacillin does not work against fungi.

If you get severe skin reactions with painful red areas, large blisters, peeling of skin layers; fever, chills, aching muscles, feeling unwell (signs of drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalised exanthematous pustulosis (AGEP), Stevens-Johnson Syndrome or toxic epidermal necrolysis), stop taking this medicine immediately and tell your doctor.

Things you must not do

Do not take any medicine for diarrhoea without first checking with your doctor or pharmacist.

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking flucloxacillin.

Flucloxacillin treats infections in most people, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

IMPORTANT: Flucloxacillin can cause severe liver damage, which can make the skin and whites of the eyes turn yellow in colour. This is more likely to occur in older patients particularly those over 55 years of age and those who take it for more than 14 days.

Immediately contact your doctor if you notice any yellowing of your eyes or skin.

Tell your doctor or pharmacist if you notice any of the following:

- nausea
- feeling sick or vomiting
- stomach upset, diarrhoea
- a mild rash

- oral thrush (white, furry sore tongue and mouth)
- vaginal thrush (sore and itchy vagina and/or vaginal discharge).

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- tiredness, headaches, being short of breath when exercising, dizziness and looking pale (possible anaemia).

The above list includes serious side effects that may require medical attention.

If any of the following happen, stop taking your medicine and contact your doctor immediately or go to Accident and Emergency at your nearest hospital, even if they occur several weeks after stopping treatment with flucloxacillin:

- allergic reaction, symptoms of which include swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or troubled breathing; skin rash, itching or hives
- red, scaly rash with bumps under the skin and blisters
- watery and severe diarrhoea, which may also be bloody
- severe stomach cramps
- frequent infections such as fever, chills, sore throat or mouth ulcers
- convulsions or fits
- yellowing of the eyes or skin (jaundice)
- bleeding or bruising more easily than normal
- painful, swollen joints
- aching muscles, muscle tenderness or weakness, not caused by exercise
- irregular heart beat
- dark or cloudy urine, blood in the urine.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if notice anything that is making you feel unwell.

Other side effects not listed above may occur in some patients.

After stopping Flucloxacillin

Tell your doctor if your skin and/ or eyes have turned yellow (jaundice) whilst or soon after you finish taking flucloxacillin. Tell your doctor immediately if you notice any of the following side effects, even if they occur up to several weeks after finishing treatment with flucloxacillin:

- watery and severe diarrhoea, which may also be bloody
- severe abdominal cramps or stomach cramps
- fever, in combination with one or both of the above

These are rare but serious side effects.

Flucloxacillin can change the bacteria (which are normally present in the bowel and are harmless) to multiply and therefore cause the above symptoms. You may need urgent medical attention.

Storage and

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

250 mg capsule (blister pack): Size 2 capsule with blue cap and blue body printed with "F250". AUST R 226382

500 mg capsule (blister pack): Size 0 capsule with blue cap and blue body printed with "F500". AUST R 226374

Pack sizes of 24 and 48 capsules.

* Not all strengths and/or pack sizes may be available.

Ingredients

Each tablet contains 250 mg & 500 mg of flucloxacillin (as sodium) as the active ingredient.

It also contains the following:

- magnesium stearate
- titanium dioxide
- indigo carmine
- methyl hydroxybenzoate
- propyl hydroxybenzoate
- gelatin
- shellac
- isopropyl alcohol
- ethanol

This medicine does not contain gluten, lactose, sucrose, tartrazine and other azo dyes.

Sponsor

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