

FLUCLOXACILLIN

Flucloxacillin (as the sodium salt) 250 mg and 500 mg capsules

Flucloxacillin (as the sodium salt) 125 mg/5 mL and 250 mg/5 mL powder for oral solution

What is in this leaflet

Please read this leaflet carefully before you start using FLUCLOXACILLIN.

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 and benefits. Your doctor has weighed the risks of you using FLUCLOXACILLIN against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What FLUCLOXACILLIN is used for

FLUCLOXACILLIN contains the active ingredient flucloxacillin. Flucloxacillin is an antibiotic that belongs to a group of medicines called penicillins. These medicines work by killing the bacteria that are causing infection.

FLUCLOXACILLIN is used to treat infections caused by bacteria. Examples of some of the infections that may be caused by bacteria include respiratory tract infections and skin or fleshy tissue skin infections.

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

Your doctor may have prescribed FLUCLOXACILLIN for another reason.

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

There is no evidence that FLUCLOXACILLIN is addictive.

FLUCLOXACILLIN is available only with a doctor's prescription.

Before you take FLUCLOXACILLIN

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 FLUCLOXACILLIN if you are allergic to:

- medicines containing flucloxacillin or any other penicillin;
- cephalosporin antibiotics;
- beta-lactam antibiotics;
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.

Do not take FLUCLOXACILLIN if you have had a reaction that has affected your liver while you were taking a medicine containing flucloxacillin. Examples of liver reactions include hepatitis and jaundice (yellowing of the eyes or skin).

Do not take FLUCLOXACILLIN if the expiry date has passed.

If you are not sure whether you should start using FLUCLOXACILLIN, talk to your doctor.

Before you start to take it

Talk to your doctor or pharmacist before taking this medicine:

If you are taking or will be taking paracetamol

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.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have any medical conditions, especially the following:

- liver problems;
- kidney problems;
- asthma, hay fever, eczema or other allergic conditions.

Tell your doctor if you are pregnant or plan to become pregnant. Your doctor will discuss the risks and benefits of taking FLUCLOXACILLIN during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed. A very small quantity of FLUCLOXACILLIN passes into breast milk. Your doctor will discuss the risks and benefits of taking FLUCLOXACILLIN when breastfeeding.

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

This medicine may cause undesirable effects (e.g. allergic reactions, dizziness) which may influence the ability to drive and use machines. You should be cautious when driving or operating machinery.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking FLUCLOXACILLIN.

Some medicines may interfere with FLUCLOXACILLIN. These include:

- probenecid, a medicine used for gout;
- some antibiotics, such as tetracycline and macrolide antibiotics.

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

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.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking FLUCLOXACILLIN.

How to take FLUCLOXACILLIN

How much to take

Your doctor will tell you how much you need to take each day and when to take it. This depends on your condition and whether or not you are taking any other medicines.

For most infections, the usual adult dose is 250 mg every six hours, however, this will depend on the severity of the infection.

If you have kidney problems, your doctor may tell you to take a lower dose.

Follow all directions given to you by your doctor carefully.

How to take FLUCLOXACILLIN

Swallow the capsules whole with a glass of water.

Take FLUCLOXACILLIN on an empty stomach, for example, half to one hour before meals or just before you go to bed. Food can interfere with the absorption of FLUCLOXACILLIN.

How long to take it

Keep taking FLUCLOXACILLIN until you finish the pack, or for as long as your doctor recommends.

Do not stop taking FLUCLOXACILLIN, 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 FLUCLOXACILLIN

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

Otherwise, take the missed dose as soon as you remember, and then go back to taking your capsules as you would normally.

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

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

While you are taking FLUCLOXACILLIN

Things you must do

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking FLUCLOXACILLIN.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking FLUCLOXACILLIN.

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 first 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 have to have any blood tests tell your doctor you are taking FLUCLOXACILLIN. FLUCLOXACILLIN may affect the results of some blood tests.

If you are taking FLUCLOXACILLIN for a long time, visit your doctor regularly so that they can check on your progress.

You may need to have tests to check your liver.

Things you must not do

Do not use FLUCLOXACILLIN to treat any other conditions unless your doctor tells you to.

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

Do not stop taking FLUCLOXACILLIN, even if you feel better after a few days, unless advised by your doctor. If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much FLUCLOXACILLIN.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include nausea, vomiting and diarrhoea.

Side effects

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 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 as soon as possible if you do not feel well while you are using FLUCLOXACILLIN. FLUCLOXACILLIN treats infections in most people however; it may cause 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 treatment if you get some of the adverse effects.

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

Very rare side effects (may affect up to 1 in 10,000 people): 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 Before you take FLUCLOXACILLIN)

Tell your doctor if you notice any of the following and they worry you:

- feeling sick or vomiting;
- stomach upset, diarrhoea;
- oral thrush (white, furry sore tongue and mouth);

- vaginal thrush (sore and itchy vagina, vaginal discharge).

These are the more common side effects of FLUCLOXACILLIN. Mostly these are mild and short-lived.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- watery and severe diarrhoea, which may also be bloody;
- severe stomach cramps;
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale;
- bleeding or bruising more easily than normal;
- frequent infections such as fever, chills, sore throat or mouth ulcers;
- yellowing of the eyes or skin (jaundice);
- painful, swollen joints;
- aching muscles, muscle tenderness or weakness, not caused by exercise;
- dark or cloudy urine, blood in the urine.

These may be serious side effects of FLUCLOXACILLIN. You may need urgent medical attention. These serious side effects are very rare.

If any of the following happen, stop taking FLUCLOXACILLIN and tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- skin rash, itching or hives;
- swelling of the face, lips, tongue or other parts of the body;
- shortness of breath, wheezing or troubled breathing.

If you experience any of these side effects, you may have had a serious allergic reaction to FLUCLOXACILLIN. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor immediately if you notice any of the following, even if they occur several weeks after stopping treatment with FLUCLOXACILLIN:

- watery and severe diarrhoea, which may also be bloody;
- severe stomach cramps;
- yellowing of the eyes or skin (jaundice).

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using FLUCLOXACILLIN

Storage

Keep FLUCLOXACILLIN where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground are a good place to store medicines.

Keep FLUCLOXACILLIN tablets in a cool, dry place where the temperature stays below 25 °C.

Keep FLUCLOXACILLIN mixture in the refrigerator but not in the freezer.

Do not use any mixture left in the bottle after 14 days.

Do not store FLUCLOXACILLIN or any other medicine in the bathroom or near a sink. Do not leave FLUCLOXACILLIN in the car or on windowsills. Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

FLUCLOXACILLIN is available in capsules or as syrup.

FLUCLOXACILLIN capsules are grey/caramel coloured.

FLUCLOXACILLIN syrup is an opaque, off-white solution.

Ingredients

The active ingredient in FLUCLOXACILLIN capsules and syrup is flucloxacillin (as flucloxacillin sodium).

FLUCLOXACILLIN capsules come in two strengths:

- FLUCLOXACILLIN 250 mg: each capsule contains 250 mg of flucloxacillin as the sodium salt.
- FLUCLOXACILLIN 500 mg: each capsule contains 500 mg of flucloxacillin as the sodium salt.

The capsules also contain:

- Gelatin;
- Silicon dioxide;
- Magnesium stearate.

The capsules are gluten and lactose free.

FLUCLOXACILLIN syrup comes in two strengths. When prepared correctly, the syrup will contain the following:

- Flucloxacillin Oral Solution 125 mg/5 mL: each 5 mL of solution contains 125 mg flucloxacillin as the sodium salt.
- Flucloxacillin Oral Solution 250 mg/5 mL: each 5 mL of solution contains 250 mg flucloxacillin as the sodium salt.

The syrup also contains:

- Citric acid;
- Disodium edetate;
- Lemon, menthol and strawberry flavours;
- Menthol flavour;
- Saccharin sodium;
- Silicon dioxide;
- Sodium benzoate;
- Sodium citrate;
- Sorbitol;
- Xanthan gum.

Sponsor details

FLUCLOXACILLIN is supplied in New Zealand by:

AFT Pharmaceuticals Ltd
PO Box 33-203
Takapuna
Auckland 0740

Telephone: 0800 423 823

Date of preparation

This leaflet was revised in August 2019.