

FLUCIL Injection

Flucloxacillin sodium monohydrate

500 mg & 1 g, powder for injection

What is in this leaflet

Please read this leaflet carefully before you start using FLUCIL.

This leaflet answers some common questions about FLUCIL. 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 FLUCIL 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 FLUCIL is used for

FLUCIL is an antibiotic that belongs to a group of medicines called penicillins. These antibiotics work by killing the bacteria that are causing your infection.

FLUCIL is an antibiotic used to treat some infections in different parts of the body caused by bacteria. It is used to:

- treat skin and soft tissue infections caused by bacteria which are resistant to penicillin.

e.g. infections of the joints, respiratory tract, urinary tract, inflammation (pain, heat, swelling or redness) of the middle ear, inflammation of the endocardium (a membrane that covers the inside surface of the heart), infected blood and meningitis.
- prevent infections resulting from surgery, in particular chest, bone and joint procedures.

Flucil is also used in the prophylaxis of staphylococcal infections during major surgical procedures, particularly in cardiothoracic or orthopaedic surgery.

FLUCIL will not work against infections caused by viruses, such as colds.

Your doctor may have prescribed FLUCIL for another reason.

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

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

There is no evidence that FLUCIL is addictive.

Before you are given FLUCIL

When you must not be given FLUCIL

Do not use FLUCIL if:

- your skin and/or eyes have turned yellow (Jaundice) while, or soon after receiving flucloxacillin (FLUCIL).
- you are allergic to flucloxacillin, other penicillins or any of the ingredients listed at the end of this leaflet.
Some of the symptoms of an allergic reaction may include skin rash, itching, hayfever, swelling and difficult breathing.
- you have had an allergic reaction to cephalosporins.
- you may have an increased chance of being allergic to FLUCIL if you are allergic to cephalosporins.

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

Before you are given FLUCIL

Flucloxacillin (FLUCIL) can cause jaundice (yellowing of skin and/or eyes) and severe liver disease which may last for a long time. This reaction is more frequent in older patients (particularly those over 55 years of age) and those who receive the drug for more than 14 days.

Tell your doctor if:

- you have an allergy to FLUCIL or other penicillins.
- you have had any type of allergic reaction to cephalosporin medicines.
You may have an increased chance of being allergic to FLUCIL if you are allergic to cephalosporins.
- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes. This may include medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.
- your skin and/or eyes have turned yellow (Jaundice) while, or soon after, receiving any antibiotics.

- you have or have ever had any other health problems/medical conditions, including:
 - kidney or liver disease
 - asthma, hayfever or hives
 - glandular fever (infectious mononucleosis).
- you are pregnant or intend to become pregnant.
Your doctor will discuss the risks and benefits of using FLUCIL during pregnancy.
- you are breast-feeding or plan to breast-feed.
Your doctor will discuss the risks and benefits of using FLUCIL when breast-feeding.

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

Special care should be taken in new-born or premature babies to avoid overdose or high levels of bilirubin, a chemical in the blood which can lead to brain damage.

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 FLUCIL.

Some medicines may interfere with FLUCIL. These include:

- probenecid - a medicine used to treat gout.
- antibiotics such as chloramphenicol, erythromycin, sulphonamides or tetracyclines.
- estrogen containing oral contraceptives - if you are using this type of medicine you should take additional precautions to prevent pregnancy.
- Aminoglycosides - If FLUCIL and an aminoglycoside are to be used simultaneously, the two antibiotics should not be mixed together.
- Methotrexate - medicine taken to treat cancer or autoimmune disorders.
- Warfarin - medicine to prevent blood clotting.
- Voriconazole and Posaconazole - medicine used to treat fungal infections.
- Paracetamol - caution is advised when FLUCIL is administered concomitantly with paracetamol due to the increased risk of high anion gap metabolic acidosis.

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

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

FLUCIL should not be mixed with blood products or other fluids containing protein.

How FLUCIL is given

FLUCIL may be given in two ways:

- as a slow injection into a vein
- as a deep injection into a large muscle, a joint or the sac surrounding the lung.

FLUCIL must only be given by a doctor or nurse.

Your doctor will decide what the dose is and for how long you will receive FLUCIL. This depends on your infection and other factors, such as your weight. For most infections, FLUCIL is usually given in divided doses throughout the day. Sometimes only a single dose of FLUCIL is required for the treatment and prevention of certain infections.

After you have been given FLUCIL

Things you must do

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

If you develop itching with swelling or skin rash or difficulty breathing after you have been given FLUCIL, contact your doctor immediately.

If you develop yellow eyes and/or skin (jaundice) while, or soon after receiving FLUCIL, contact your doctor immediately.

If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs up to several weeks after FLUCIL has been stopped. 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 after you have been given FLUCIL, tell your doctor. Also tell your doctor if you get a vaginal itching or discharge. This may mean you have a fungal infection called thrush. Sometimes the use of FLUCIL allows fungi to grow and the above symptoms to occur. FLUCIL does not work against fungi.

If you become pregnant while you are receiving FLUCIL, tell your doctor.

If you have to have any tests tell your doctor you have been given FLUCIL. FLUCIL may affect the results of some tests.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are receiving FLUCIL.

Tell any doctor, dentist or pharmacist who is treating you that you have been given FLUCIL.

During prolonged therapy, your doctor should carry out periodic tests to assess kidney and liver function and blood cell formation.

Be aware that superinfections may occur.

This is a new infection resulting from the invasion of bacteria resistant to flucloxacillin. FLUCIL should be discontinued and another therapy commenced.

Things to be careful of

Be careful before you drive or use any machines or tools until you know how FLUCIL affects you.

FLUCIL generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, FLUCIL may cause dizziness, drowsiness or tiredness in some people.

If you experience dizziness, do not drive.

If you drink alcohol, dizziness may be worse.

In case of overdose

If you take too much (overdose)

As FLUCIL injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience severe side effects after being given this medicine, tell your doctor immediately.

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 FLUCIL.

Do this even if there are no signs of discomfort or poisoning.

A very large overdose of FLUCIL can cause brain upsets, including fits.

Side Effects

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

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.

Whilst being given FLUCIL

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

- a severe rash
- wheezing
- irregular heart beat
- feeling faint
- yellow skin and/or eyes
- a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck.

Also tell your doctor if you notice:

- pain or redness at the site of injection
- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina and/or discharge
- a mild rash

Other side effects not listed above may also occur in some patients. These include very rare conditions such as blood, liver and kidney problems or fits.

After finishing FLUCIL

Tell your doctor if your skin and/or eyes have turned yellow (Jaundice) while or soon after receiving flucloxacillin (FLUCIL).

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after finishing treatment with FLUCIL:

- severe abdominal cramps or stomach cramps

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

These are rare but serious side effects. FLUCIL can change bacteria (which are normally present in the bowel and normally harmless) to multiply and therefore cause the above symptoms. You may need urgent medical attention.

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

An illness consisting of a rash, swollen glands, joint pains and fever may occur about a week after treatment.

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 receiving FLUCIL

Storage

FLUCIL must be kept out of reach and sight of children.

FLUCIL injection is usually stored in the pharmacy or on the ward. Your doctor, pharmacist or nurse is responsible for storing FLUCIL and disposing of any unused product correctly.

Store it in a cool dry place where the temperature stays below 25°C.

Product description

What it looks like

FLUCIL Injection is a white to off-white powder which has to be dissolved in water before it is injected.

FLUCIL is available in packs of 5 vials.

Ingredients

Active ingredient:

- 500 mg or 1 g flucloxacillin sodium monohydrate

Inactive ingredients:

- None.

FLUCIL contains no antiseptics or buffering agents nor are there any excipients.

Sponsor Details

FLUCIL is supplied in New Zealand by:

Pharmacy Retailing (NZ) Limited t/a Healthcare Logistics

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NEW ZEALAND

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