

FLUCIL Injection

Flucloxacillin sodium

What is in this leaflet

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 and pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you receiving FLUCIL against the benefits this medicine is expected to have for you.

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

Keep this leaflet. 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. Eg. 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 will not work against infections caused by viruses, such as colds.

Your doctor may have prescribed FLUCIL for another reason. Ask your doctor 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 it

Do not use FLUCIL if:

- your skin and/or eyes have turned yellow (Jaundice) while, or soon after receiving flucloxacillin (FLUCIL).
 - you have an allergy to FLUCIL or other penicillins.
 - 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 be given FLUCIL, talk to your doctor.
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Before you are given it

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.

You must tell your doctor if:

- 1. you have an allergy to FLUCIL or other penicillins.**
- 2. 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.
- 3. 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.
- 4. your skin and/or eyes have turned yellow (Jaundice) while, or soon after, receiving any antibiotics.**
- 5. you have or have ever had any other health problems/medical conditions, including kidney or liver disease.**
- 6. you are pregnant or intend to become pregnant.**
Your doctor will discuss the risks and benefits of using FLUCIL during pregnancy.
- 7. 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 him/her before you are given FLUCIL.

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. Some medicines may interfere with FLUCIL.

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

- probenecid – a medicine used to treat gout (excess uric acid in the blood). Probenecid may increase the concentration of flucloxacillin in the body. This can be of benefit in the treatment of some infections.
- antibiotics such as chloramphenicol, erythromycin, sulphonamides or tetracyclines. These antibiotics may interfere with the effect of penicillins in the treatment of meningitis or other diseases where rapid action is necessary. Simultaneous therapy is best avoided.
oestrogen containing oral contraceptives – using FLUCIL while on contraceptives may decrease the effectiveness of the contraceptive. . Talk to your doctor about the need for an additional method of contraception whilst receiving FLUCIL.
- Aminoglycosides – If FLUCIL and an aminoglycoside are to be used simultaneously, the two antibiotics should not be mixed together.
- 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.

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 whilst receiving FLUCIL.

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.

If you have too much (overdose)

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

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.

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

Caution should be exercised when administering FLUCLOXIN to newly born or premature babies.

Flucloxacillin may cause hyperbilirubinaemia (high levels of bilirubin in the blood). Bilirubin is produced when red blood cells are broken down. Usually the liver processes bilirubin but in new born and premature babies, the liver is not fully developed. High levels of bilirubin will cause jaundice and may lead to brain damage. Babies using FLUCLOXIN must be monitored closely.

FLUCLOXIN remains in the body longer in newly born babies and the elderly due to incomplete or decreased kidney function.

They are more likely to experience side effects.

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. FLUCLOXIN should be discontinued and another therapy commenced.

Things to be careful of

Be careful driving or operating machinery 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.

Side Effects

Check with your doctor as soon as possible if you have any problems whilst receiving FLUCIL, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, FLUCIL can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

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.

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

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.

Tell your doctor if you notice any side effects.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known. Ask your doctor or pharmacist if you are concerned.

After receiving FLUCIL

Storage

Keep FLUCIL in a cool dry place where the temperature stays below 25°C.

Shelf Life

36 months

FLUCIL 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.

Ingredients

Flucloxacillin sodium, 500 mg and 1 g.

The Australian Registration Numbers are:

500mg	AUST R 90879
1g	AUST R 90878

Sponsor Details

Aspen Pharmacare Australia Pty Limited
34-36 Chandos Street, St Leonards 2065
NSW Australia

FLUCIL is supplied in New Zealand by:
Pharmacy Retailing (NZ) Limited trading as Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland
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Date of Preparation

March 2020