

FLUBICLOX™ for Injection

Flucloxacillin for Injection (floo-klox-s-SILL-in)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FLUBICLOX.

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 taking FLUBICLOX against the benefits this medicine is expected to have for you.

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

Keep this leaflet in a safe place

You may need to read it again.

What is FLUBICLOX used for

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

FLUBICLOX, like other antibiotics, will not work against infections caused by viruses such as colds or the flu.

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

Before you are given FLUBICLOX

When you must not be given it

Do not use FLUBICLOX if:

1. You have had an allergic reaction to flucloxacillin or other penicillins. Symptoms of an allergic reaction may include skin rash, itching, difficulty breathing or swelling.
2. You have had an allergic reaction to cephalosporin antibiotics. You may have an increased chance of being allergic to FLUBICLOX if you are allergic to cephalosporins.
3. You have a previous history of inflammation of the liver or yellow skin caused by flucloxacillin.
4. The packaging is torn or shows signs of tampering.
5. The expiry date (exp) printed on the pack has passed. If you use this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be given FLUBICLOX, talk to your doctor

WARNING

Liver Toxicity. FLUBICLOX can cause severe inflammation of the liver and yellow skin, which may be long lasting. This reaction is more frequent in older patients and those who take the drug for long periods.

Before you are given it

Tell your doctor or pharmacist if:

1. You have any type of allergic reaction to penicillin, amoxicillin or cephalosporin antibiotics.

You may have an increased chance of being allergic to FLUBICLOX if you are allergic to cephalosporins.

2. You have any allergies to any other medicines or any other substances such as foods, preservatives or dyes.
3. You have, or have ever had, any other medical conditions including:
 - asthma, hayfever or hives
 - liver problems
 - kidney problems
 - glandular fever (infectious mononucleosis)
4. **You are pregnant or intend to become pregnant.** Your doctor will discuss the possible risks and benefits of using FLUBICLOX during pregnancy.
5. **You are breast-feeding or plan to breast-feed.** Your doctor will discuss the possible risks and benefits of using FLUBICLOX while breast-feeding.

If you have not told your doctor or pharmacist any of the above, tell them before you are given FLUBICLOX.

Taking other medications

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

Some medicines may be affected by FLUBICLOX, or they may affect how well it works.

These include:

- probenecid, a medicine used to treat gout

- aminoglycosides; a group of antibiotic medicines used to treat some infections.

You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor will advise you.

Your doctor may have more information on medicines to be careful with or to avoid while taking FLUBICLOX.

How FLUBICLOX is given

FLUBICLOX is available in three strengths – 500mg, 1g and 2g.

FLUBICLOX 500mg and 1g injection is diluted and then given:

- as an injection into a vein
- as a deep injection into a large muscle
- in fluids given into a vein
- into the space around the lungs
- within a joint

FLUBICLOX 2g injection is diluted and then given:

- as an injection into a vein
- in fluids given into a vein

FLUBICLOX must only be given by a doctor or nurse.

Your doctor will decide what dose and how long you will receive FLUBICLOX.

This depends on your infection and other factors, such as your weight. For most infections, FLUBICLOX is usually given in divided doses throughout the day.

If you receive too much (overdose)

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

You may need urgent medical attention.

Symptoms of an overdose may include the side effects listed below in the ‘Side Effects’ section, but are usually of a more severe nature.

While you are being given FLUBICLOX

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 while you are receiving FLUBICLOX, do not have any more and tell your doctor immediately.

If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after FLUBICLOX 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 while being treated with or soon after stopping FLUBICLOX, 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 FLUBICLOX allows fungi to grow and the above symptoms to occur.

FLUBICLOX does not work against fungi.

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

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

If you have to have any blood or urine tests, tell your doctor you are being given FLUBICLOX.

FLUBICLOX may affect the results of some blood or urine tests.

Tell all the doctors dentists and pharmacists who are treating you that you are being given FLUBICLOX.

Things to be careful of

Be careful driving or operating machinery until you know how flucloxacillin affects you.

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

If you experience dizziness, do not drive.

If you drink alcohol, dizziness may be worse.

Side effects

Check with your doctor as soon as possible if you have any problems while being treated with FLUBICLOX, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, FLUBICLOX 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.

If you are over 65 years of age you may have an increased chance of getting side effects.

You may not experience any of them.

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

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

- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina and/or discharge
- nausea, stomach upsets
- mild diarrhoea or constipation
- dizziness or headaches
- pain or an uncomfortable feeling in the stomach or belching after eating.

The above list includes side effects which are usually mild.

Tell your doctor immediately if you notice any of the following:

- signs of an allergic reaction, such as shortness of breath wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body
- red and/or itchy skin, rash or hives on the skin
- difficulty breathing
- swelling
- yellowing of the skin and/or eyes (these may be symptoms of a type of liver disease called jaundice)
- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching and dark coloured urine (these may be symptoms of a type of liver disease called hepatitis)

The above list includes very serious side effects. You may need urgent medical attention. Serious side effects are rare.

Some people may get other side effects while being treated with FLUBICLOX.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

After using FLUBICLOX

Storage

FLUBICLOX should be stored in the pharmacy or in the ward. The powder for injection is kept in a cool dry place where the temperature stays below 25°C.

After you finish using it

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

- severe stomach cramps or abdominal 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.

You may have a rare but serious condition affecting your bowel which may need urgent medical attention.

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

Product description

What it looks like

White or almost white crystalline powder for injection contained in a vial.

500 mg: 5, 10's

1 g: 5, 10's

2 g: 1, 10

Ingredients

Active ingredient:

Flucloxacillin as sodium

FLUBICLOX does not contain any other ingredients.

FLUBICLOX does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Australian Sponsor:

Juno Pharmaceuticals Pty Ltd
42 Kelso Street,
Cremorne
VIC – 3121
Australia

FLUBICLOX is available in the following strengths:

Strength	AUST R
2 g	302381
1 g	92842
500 mg	92841

This leaflet was prepared in: January 2020.