

FLUBICLOX Injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I being given FLUBICLOX?

FLUBICLOX contains the active ingredient flucloxacillin sodium monohydrate. FLUBICLOX is an antibiotic used to treat some infections in different parts of the body caused by bacteria.

For more information, see Section [1. Why am I being given FLUBICLOX?](#) in the full CMI.

2. What should I know before I am given FLUBICLOX?

Do not use if you have ever had an allergic reaction to FLUBICLOX, other penicillins or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given FLUBICLOX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FLUBICLOX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given FLUBICLOX?

FLUBICLOX will be given to you by a doctor or nurse. Your doctor will decide what the dose is 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.

More instructions can be found in Section [4. How am I given FLUBICLOX?](#) in the full CMI.

5. What should I know after receiving FLUBICLOX?

Things you should do	<ul style="list-style-type: none">• 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 FLUBICLOX, contact your doctor immediately.• If you develop yellow eyes and/or skin (jaundice) while, or soon after receiving FLUBICLOX, 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 FLUBICLOX has been stopped.• If you get a sore white mouth or tongue after you have been given FLUBICLOX, tell your doctor. Also tell your doctor if you get a vaginal itching or discharge.• If you become pregnant while you are receiving FLUBICLOX, tell your doctor.• If you have to have any tests tell your doctor you have been given FLUBICLOX.• Remind any doctor, dentist or pharmacist you visit that you are being treated with FLUBICLOX.
Things you should not do	<ul style="list-style-type: none">• Do not take any diarrhoea medicine without first checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how FLUBICLOX affects you.

For more information, see Section [5. What should I know after receiving FLUBICLOX?](#) in the full CMI.

6. Are there any side effects?

Side effects include pain or redness at the site of injection, mild rash, oral thrush, vaginal thrush, nausea, stomach upsets, mild diarrhoea, constipation, dizziness or headaches.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

FLUBICLOX

Active ingredient(s): flucloxacillin (as sodium)

Consumer Medicine Information (CMI)

This leaflet provides important information about using FLUBICLOX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FLUBICLOX.**

Where to find information in this leaflet:

- [1. Why am I being given FLUBICLOX?](#)
- [2. What should I know before I am given FLUBICLOX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given FLUBICLOX?](#)
- [5. What should I know after receiving FLUBICLOX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given FLUBICLOX?

FLUBICLOX contains the active ingredient flucloxacillin (as flucloxacillin sodium). 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 is an antibiotic used to treat some infections in different parts of the body caused by bacteria.

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

Your doctor may have prescribed FLUBICLOX for another reason.

There is no evidence that FLUBICLOX is addictive.

2. What should I know before I am given FLUBICLOX?

Warnings

Do not use FLUBICLOX if:

- your skin and/or eyes have turned yellow (Jaundice) while, or soon after receiving flucloxacillin (FLUBICLOX).
- 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, difficult breathing or swelling.
- 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.
- the packaging is torn or shows signs of tampering.
- 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.

WARNING

Flucloxacillin (FLUBICLOX) 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.

Check with your doctor if 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.
- 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.
- Have or have ever had any other medical conditions including:
 - asthma, hayfever or hives
 - liver problems
 - kidney problems
 - glandular fever (infectious mononucleosis)
- your skin and/or eyes have turned yellow (Jaundice) while, or soon after, receiving any antibiotics.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or breastfeeding, intend to become pregnant or breastfeed. Your doctor will discuss with you whether you can be given FLUBICLOX.

3. What if I am taking other medicines?

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

Some medicines may interfere with FLUBICLOX and affect how it works. These include:

- probenecid (Benemid)
- paracetamol
- aminoglycosides.

Some antibiotics may decrease the effectiveness of some birth control pills. Talk to your doctor about the need for an additional method of contraception whilst receiving FLUBICLOX.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FLUBICLOX.

4. How am I given FLUBICLOX?

How much is given

- your doctor will decide what the dose is and for 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. Sometimes only a single dose of FLUBICLOX is required for the treatment and prevention of certain infections.

How FLUBICLOX is given

FLUBICLOX may be given in two ways:

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

FLUBICLOX must only be given by a doctor or nurse.

If you use too much FLUBICLOX

As FLUBICLOX 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

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

5. What should I know after receiving FLUBICLOX?

Things you should do

Call your doctor straight away if:

- the symptoms of your infection do not improve within a few days, or if they become worse.
- you develop itching with swelling or skin rash or difficulty breathing after you have been given FLUBICLOX.
- you develop yellow eyes and/or skin (jaundice) while, or soon after receiving FLUBICLOX.
- you get severe diarrhoea. Do this even if it occurs up to 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.

- you get a sore white mouth or tongue after you have been given FLUBICLOX. 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 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 have to have any tests, tell your doctor you have been given FLUBICLOX. FLUBICLOX 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 FLUBICLOX. Remind any doctor, dentist or pharmacist you visit that you are being treated FLUBICLOX.

Things you should not do

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

Driving or using machines

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

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

If you experience dizziness, do not drive.

If you drink alcohol, dizziness may be worse.

Looking after your medicine

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

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

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Pain or redness at the site of injection• oral thrush – white, furry, sore tongue and mouth	Speak to your doctor if you have any of these less serious side

<ul style="list-style-type: none"> vaginal thrush - sore and itchy vagina and/or discharge nausea or vomiting upset stomach or belching after eating mild diarrhoea or constipation dizziness or headache a mild rash. Pain in the joints. 	effects and they worry you.
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> signs of allergic reaction, e.g. shortness of breath, wheezing, difficulty breathing, swelling of face, lips, tongue or other parts of the body red and/or itchy skin, severe rash or hive on the skin irregular heart beat yellow skin and/or eyes nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching and dark coloured urine (this may be symptoms of hepatitis). 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Other side effects not listed here may occur in some people.

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

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What FLUBICLOX contains

Active ingredient (main ingredient)	Flucloxacillin sodium
Other ingredients	None

(inactive ingredients)	
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FLUBICLOX Powder for Injection contains no antiseptics or buffering agents nor are there any excipients.

Do not take this medicine if you are allergic to any of these ingredients.

What FLUBICLOX looks like

FLUBICLOX Injection is a white or almost white crystalline powder for injection contained in a clear glass vial. FLUBICLOX Injection is available in

500 mg (AUST R: 92841); Pack size: 5, 10's

1 g (AUST R 92842); Pack size: 5, 10's

2 g: (AUST R 302381) Pack size: 1, 10's

Who distributes FLUBICLOX

Juno Pharmaceuticals Pty Ltd,
42 Kelso Street,
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Australia

www.junopharm.com.au

This leaflet was prepared in September 2023.