FLUCIL Oral Solution

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 using FLUCIL?

FLUCIL contains the active ingredient flucloxacillin sodium monohydrate. FLUCIL 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 using FLUCIL? in the full CMI.

2. What should I know before I use FLUCIL?

Do not use if you have ever had an allergic reaction to FLUCIL, 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 use FLUCIL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FLUCIL 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 do I use FLUCIL?

Your doctor will choose the correct dose for you. Follow all directions given to you by your doctor and pharmacist carefully. More instructions can be found in Section 4. How do I use FLUCIL? in the full CMI.

5. What should I know while using FLUCIL?

Things you should 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 taking FLUCIL, do not take any more and contact your doctor immediately. If you develop yellow eyes and/or skin (jaundice) while, or soon after taking 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. If you get a sore white mouth or tongue while taking FLUCIL, tell your doctor. Also tell your doctor if you get a vaginal itching or discharge. If you become pregnant while you are receiving FLUCIL, tell your doctor. If you have to have any tests tell your doctor you are taking FLUCIL. Remind any doctor, dentist or pharmacist you visit that you are taking FLUCIL.
Things you should not do	 Do not take any diarrhoea medicine without first checking with your doctor. Do not give FLUCIL to anyone else, even if they have the same condition as you. Do not take FLUCIL to treat any other complaints unless your doctor tells you to.
Driving or using machines	Be careful driving or operating machinery until you know how FLUCIL affects you.
Looking after your medicine	 Store FLUCIL Oral Solution below 25°C. Reconstituted FLUCIL Oral Solution should be stored between 2-8°C and used within 14 days.

For more information, see Section 5. What should I know while using FLUCIL? in the full CMI.

6. Are there any side effects?

Side effects include 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.

FLUCIL Oral Solution

Active ingredient: flucloxacillin sodium monohydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using FLUCIL. 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 FLUCIL.

Where to find information in this leaflet:

- 1. Why am I using FLUCIL?
- 2. What should I know before I use FLUCIL?
- 3. What if I am taking other medicines?
- 4. How do I use FLUCIL?
- 5. What should I know while using FLUCIL?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using FLUCIL?

FLUCIL contains the active ingredient flucloxacillin (as flucloxacillin sodium monohydrate). 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.

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

Ask your doctor why FLUCIL has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that FLUCIL is additive.

2. What should I know before I use FLUCIL?

Warnings

Do not use FLUCIL if:

- your skin and/or eyes have turned yellow (Jaundice) while, or soon after taking 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, difficult breathing or swelling.

Always check the ingredients to make sure you can use this medicine.

- 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.
- the packaging is torn or shows signs of tampering.
- the expiry date (EXP) printed on the pack has passed.

WARNING

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.

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 FLUCIL 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:
 - o asthma, hayfever or hives
 - o liver problems
 - o kidney problems
 - o 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 take FLUCIL.

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 FLUCIL and affect how it works. These include:

- probenecid
- 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 FLUCIL.

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

4. How do I use FLUCIL?

How much to take

- your doctor will choose the correct dose for you.
- The usual dose for adults is 250 mg every 6 hours, but this can be increased in severe infections. Children between 2 & 10 years of age should have half the adult dose and infants below 2 years of age should be given a quarter of the adult dose.
- your pharmacist will explain how many mLs of syrup will be needed to receive the correct dose.
- follow all directions given to you by your doctor and pharmacist carefully.
 - These directions may differ from the information contained in this leaflet.

When to take FLUCIL

 FLUCIL Oral Solution should be taken 30 minutes to 1 hour before food. If you are too ill to eat, take the medicine when it is due.

How to take FLUCIL

· FLUCIL Oral Solution is taken orally.

If you forget to use FLUCIL

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 it as soon as you remember, and then go back to taking FLUCIL as you would normally. If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

If you have trouble remembering when to take FLUCIL, ask your pharmacist for some hints.

If you use too much FLUCIL

If you think that you have used too much FLUCIL, you may need urgent medical attention.

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.

Symptoms of an overdose may include diarrhoea and nausea.

5. What should I know while using FLUCIL?

Things you should do

Call your doctor straight away if:

- your symptoms do not improve within a few days, or if they become worse.
- you develop itching with swelling or skin rash or difficulty breathing soon after taking FLUCIL. Stop taking this medicine immediately and tell your doctor.
- you develop yellow eyes or skin (jaundice) whilst or soon after taking FLUCIL. Do this even if it occurs several weeks after you have stopped taking FLUCIL.
 Jaundice may mean that you have a serious condition affecting your liver. You may need urgent medical care.
- you get severe diarrhoea. 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.
- you get a sore white mouth or tongue while taking or soon after stopping FLUCIL. 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.
- you become pregnant while taking this medicine.

Before starting any new medicine, remind your doctor and pharmacist that you are using FUCIL.

Remind any doctor, dentist or pharmacist you visit that you are taking FLUCIL.

If you have to have any tests, tell your doctor you are taking FLUCIL. FLUCIL may affect the results of some tests.

If you are taking FLUCIL 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 and kidney function.

Things you should not do

- Do not give FLUCIL to anyone else, even if they have the same condition as you.
- Do not take FLUCIL to treat any other complaints unless your doctor tells you to.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.
 - If you stop taking it suddenly, your condition may worsen.
- 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 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.

Looking after your medicine

- Keep the solution in the bottle until it is time to take it.
- The mixture should be stored between 2-8°C and used within 14 days.

Keep it where young children cannot reach it.

When to discard your medicine

Discard any mixture remaining when the treatment is completed.

Discard any mixture which is not used within 14 days.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Once the pharmacist has made up the solution, it must be used within 14 days.

Do not use this medicine after the expiry date.

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.

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

Less serious side effects

Less serious side effects	What to do
 oral thrush – white, furry, sore tongue and mouth 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. 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
• signs of allergic reaction, e.g. shortness of breath, wheezing, difficulty breathing, swelling of face, lips or tongue or other parts of the body	Call your doctor straight away, or go straight to the Emergency Department at

- 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)

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 FLUCIL contains

Active ingredient (main ingredient)	flucloxacillin sodium monohydrate
Other ingredients	ammonium glycyrrhizinate
(inactive ingredients)	disodium edetate
	erythrosine
	menthol flavour PI (11940) pineapple flavour PI (12542)
	saccharin sodium
	sodium benzoate
	sodium citrate
	sucrose

Each gram of flucloxacillin sodium monohydrate contains 2.2 mmol of sodium.

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

What FLUCIL looks like

FLUCIL is supplied to the pharmacist as a powder which is made up into 125 mg/5 mL (AUST R 165731) or 250 mg/5 mL (AUST R 165005) pineapple-flavoured solution.

Who distributes FLUCIL

Aspen Pharmacare Australia Pty Ltd 34-36 Chandos Street, St Leonards NSW 2065 Australia www.aspenpharmacare.com.au

This leaflet was prepared in June 2023.