

APO-Flucloxacillin

Contains the active ingredient flucloxacillin (as flucloxacillin sodium)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about flucloxacillin. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Flucloxacillin Capsules.

It is used to treat infections in different parts of the body caused by bacteria. It contains the active ingredient flucloxacillin sodium.

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

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

How it works

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

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

There is no evidence that this medicine is addictive.

Use in children

Children 2 to 10 years can take half the adult dose.

Before you take this medicine

WARNING: Flucloxacillin can cause severe liver damage, particularly in older patients and those who take it for more than 14 days.

When you must not take it

Do not take this medicine if you are allergic to:

- medicines containing flucloxacillin or any other penicillin or any of the ingredients listed at the end of this leaflet.
- cephalosporin antibiotics
- beta-lactam antibiotics including imipenem and aztreonam

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Do not take flucloxacillin if you have had a reaction affecting your

liver while you were taking a medicine containing flucloxacillin.

Examples of liver reactions include hepatitis and jaundice (yellowing of the eyes or skin)

Do not take this medicine if the expiry date (EXP) printed on the pack has passed.

Do not take this medicine if the packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - Any other medicines.
 - Any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - Liver problems
 - Kidney problems
 - Jaundice, yellowing of the skin or eyes
 - Asthma, hayfever, eczema or other allergic conditions.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You have recently been vaccinated or plan to get a vaccination.
6. You are planning to have surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.
8. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available

from your pharmacy, supermarket or health food shop.

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

Some medicines may be affected by flucloxacillin, or may affect how well it works. Your doctor or pharmacist can tell you what to do if you are taking flucloxacillin with other medicines, such as probenecid, a medicine commonly used to treat gout. 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 taking this medicine.

Talk to your doctor about the need for additional contraception while taking flucloxacillin.

Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with flucloxacillin.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with flucloxacillin.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

For most infections, the usual dose for adults is 250 mg every 6 hours.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the capsules with a glass of water.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

Take flucloxacillin on an empty stomach, for example, half to one hour before meals and at bedtime.

Food can interfere with the absorption of flucloxacillin.

How long to take it for

Keep taking this medicine until you finish the pack, or for as long as your doctor recommends.

Do not stop taking this medicine, even if you feel better after a few days, unless advised by your doctor.

Your infection may not clear completely if you stop taking your medicine too soon.

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time.

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

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

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much flucloxacillin, you may get diarrhoea and nausea.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

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

If you develop jaundice (yellowing of the eyes or skin), tell your doctor immediately. Do this even if it

occurs several weeks after you have stopped taking flucloxacillin.

Jaundice may mean that you have a serious condition affecting your liver. You may need urgent medical care.

If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after you have stopped taking flucloxacillin.

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 checking with your doctor.

If you get a sore, white mouth or tongue while taking or soon after stopping flucloxacillin, 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 flucloxacillin allows fungi to grow and the above symptoms to occur. Flucloxacillin does not work against fungi.

If you are taking this medicine 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.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking flucloxacillin or if you have any questions or concerns.

Flucloxacillin treats infections in most people, but it may have unwanted side effects in some people.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

IMPORTANT: Flucloxacillin can cause severe liver damage, which can make the skin and whites of the eyes turn yellow in colour. This is more likely to occur in older patients and those who take it for more than 14 days. Immediately contact your doctor if you notice any yellowing of your eyes or skin.

Tell your doctor if you notice any of the following:

- feeling sick or vomiting
- stomach upset, diarrhoea
- a mild rash
- oral thrush (white, furry sore tongue and mouth)
- vaginal thrush (sore and itchy vagina and/or vaginal discharge).

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- watery and severe diarrhoea, which may also be bloody.
- severe stomach cramps.
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale (possible anaemia)
- bleeding or bruising more easily than normal
- frequent infections such as fever, chills, sore throat or mouth ulcers
- yellowing of the eyes or skin (jaundice)
- painful, swollen joints

- aching muscles, muscle tenderness or weakness, not caused by exercise
- irregular heart beat
- dark or cloudy urine, blood in the urine.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- any type of skin rash, itching or hives.
- swelling of the face, lips, tongue or other parts of the body.
- shortness of breath, wheezing or troubled breathing
- red, scaly rash with bumps under the skin and blisters (stop use and avoid in future).

Other side effects not listed above may occur in some patients.

These include very rare conditions such as blood, liver, and kidney problems or fits.

After you have finished taking this medicine

Tell your doctor immediately if you notice any of the following, even if they occur several weeks after stopping treatment with flucloxacillin:

- watery and severe diarrhoea, which may also be bloody
- severe stomach cramps
- yellowing of the eyes or skin (jaundice).

These are rare but serious side effects. Flucloxacillin 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 be alarmed by this list of possible side effects.

You may not experience any of them.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Flucloxacillin Capsules looks like

250 mg capsule: Size 2 capsule with blue cap and blue body printed with "F250".

500 mg capsule: Size 0 capsule with blue cap and blue body printed with "F500".

Pack sizes of 24 and 48 capsules.

* Not all strengths and/or pack sizes may be available.

Ingredients

Each tablet contains 250 mg & 500 mg of flucloxacillin (as sodium) as the active ingredient.

It also contains the following inactive ingredients:

- magnesium stearate
- titanium dioxide
- indigo carmine
- methyl hydroxybenzoate
- propyl hydroxybenzoate
- gelatin
- shellac
- isopropyl alcohol
- ethanol

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Flucloxacillin 250 mg capsules (blister pack) AUST R 226382

APO-Flucloxacillin 500 mg capsules (blister pack) AUST R 226374

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

APO and APOTEX are registered trade marks of Apotex Inc.

This leaflet was last updated in: October 2017