

FLOPEN® Capsules

flucloxacillin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Flopen capsules.

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

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

Keep this leaflet with the medicine. You may need to read it again.

What Flopen is used for

Flopen contains flucloxacillin (as flucloxacillin sodium) as the active ingredient.

It is used to treat infections caused by bacteria in different parts of the body.

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

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

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

Your doctor may have prescribed Flopen for another reason.

It is available only with a doctor's prescription.

There is no evidence that it is addictive.

Before you take it

When you must not be given it

Do not take Flopen if:

- **your skin and/or eyes have turned yellow (jaundice) whilst or soon after taking this medicine.**
- **you have an allergy 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 shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.

- **you have had an allergic reaction to cephalosporins.** You may have an increased chance of being allergic to Flopen if you are allergic to cephalosporins.

Do not take Flopen after the expiry date (EXP) printed on the pack.

Do not take it if the pack shows signs of having been tampered with.

Do not take this medicine to treat any other complaints unless your doctor has instructed you to do so.

Do not give this medicine to anyone else.

Before you start to take it

Tell your doctor if you are allergic to any other medicines or any foods, dyes or preservatives.

Tell your doctor if you have or have had any of the following medical conditions:

- jaundice, yellowing of the skin or eyes
- kidney or liver disease.

Do not take Flopen if you are pregnant or plan to become pregnant unless you and your doctor have discussed the risks and benefits involved.

Do not take it if you are breast feeding or plan to breast feed.

If you have not told your doctor about any of the above, tell them before you start taking Flopen.

Taking other medicines

Tell your doctor or pharmacist 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 Flopen. These include probenecid (e.g. Pro-Cid), a medicine commonly used to treat gout. These medicines may be affected by Flopen 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 taking Flopen.

Talk to your doctor about the need for an additional method of contraception whilst taking Flopen.

Some antibiotics may decrease the effectiveness of some birth control pills.

How to take it

How much to take

Your doctor will tell you how much and how often you should take Flopen capsules.

This will depend on the type of infection. The dose varies from patient to patient.

How to take it

Swallow the capsules whole with a large glass of water.

When to take it

It is best taken a half to one hour before meals. If you are too ill to eat, take the medicine when it is due.

How long to take it

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

Do not stop taking it because you are feeling better.

It is important to complete the full course prescribed by your doctor, even if you begin to feel better after a few days. If you do not, the bacteria causing your infection may not clear completely or your symptoms may return.

If you forget to take it

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 Flopen as you would normally.

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

If you are not sure what to do, talk to your doctor or pharmacist.

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

If you have too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre

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

You may need urgent medical attention.

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

While you are taking it

Things you must do

Tell your doctor if the symptoms of your infection do not improve within a few days or if they become worse.

If you develop itching with swelling or skin rash or difficulty breathing while you are taking Flopen, do not take any more and contact your doctor immediately.

Tell your doctor immediately if:

- **you develop yellow eyes or skin (jaundice) whilst or soon after taking Flopen.**
- **you get severe diarrhoea. Do this even if it occurs several weeks after Flopen 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.

Tell your doctor if:

- **you get a sore white mouth or tongue.**
 - **you get a vaginal itching or discharge.**
- This may mean you have a fungal infection called thrush. Sometimes the use of Flopen allows fungi to grow and the above symptoms to occur. Flopen does not work against fungi.
- **you become pregnant while you are taking this medicine.**

- **you have to have any blood tests.**

Flopen may affect the results of some tests.

Tell any other doctor, dentist or pharmacist who is treating you that you are taking Flopen, especially if you are being started on any new medicines.

Things you must not do

Do not give Flopen to anyone else, even if their symptoms seem similar to yours.

Do not take Flopen to treat any other complaints unless your doctor tells you to.

Things to be careful of

As with any new medicine, you should take care when driving or operating machinery until you know how Flopen affects you as it may cause dizziness, drowsiness or tiredness in some people.

Things to be aware of

Flopen 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 take the drug for more than 14 days.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Flopen.

This medicine helps most people with infection but it may have unwanted side effects in a few people.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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
- a mild rash
- vomiting or an upset stomach
- nausea
- diarrhoea.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- a severe rash
- wheezing
- irregular heart beat
- feeling faint
- jaundice, yellowing of the skin or eyes.

Other side effects not listed above may also occur in some people.

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

After finishing Flopen

Tell your doctor if your skin and/or eyes have turned yellow (jaundice) whilst or soon after taking Flopen.

Tell your doctor immediately if you notice any of the following side effects, even if they occur up to several weeks after finishing treatment with Flopen:

- 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. Flopen 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.

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

Other side effects not listed above may also occur in some people.

After taking it

Storage

Keep Flopen in a cool dry place where the temperature stays below 25 degrees C.

Do not store it in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep the capsules in the pack until it is time to take them.

If you take the capsules out of the pack they may not stay in good condition.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking Flopen or you find that the expiry date has passed, ask your pharmacist what to do with any Flopen that is left over.

Product description

What it looks like

Flopen 250 mg capsules are blue and marked "F250" in white. It is available in blister packs of 24 capsules.

Flopen 500 mg capsules are blue and marked "F500" in white. It is available in blister packs of 24 capsules.

Ingredients

Active ingredient:

Flopen capsules contain 250 mg or 500 mg flucloxacillin (as flucloxacillin sodium).

Inactive ingredients:

250 mg capsules

- magnesium stearate
- titanium dioxide
- erythrosine
- brilliant blue FCF
- sodium lauryl sulfate
- Tekprint SW-0012 (white ink)
- gelatin.

500 mg capsules

- magnesium stearate
- titanium dioxide
- erythrosine
- brilliant blue FCF
- sodium lauryl sulfate
- Tekprint SW-0012 (white ink)
- gelatin.

Flopen capsules do not contain gluten, lactose or sucrose.

Sponsor

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos St
St Leonards NSW 2065

The Australian Registration Numbers are:

250mg capsule: AUST R 209367

500mg capsule: AUST R 209368

This leaflet was revised in September 2017.