

FLOPEN

flucloxacillin (as sodium)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FLOPEN. 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 they expect it will 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

This medicine contains the active ingredient flucloxacillin.

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

It 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.

This medicine is not addictive.

It is available only with a doctor's prescription.

Before you take FLOPEN

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 FLOPEN if you have an allergy to:

- any medicine containing flucloxacillin
- any other penicillin medicines or cephalosporins
- beta-lactam antibiotics including imipenem and aztreonam
- 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

Do not take FLOPEN if you have had a reaction affecting your liver while you were taking medicine containing flucloxacillin.

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

Do not use this medicine in your eyes.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- liver problems
- kidney problems
- jaundice, yellowing of the skin or eyes
- asthma, hayfever, eczema or other allergic conditions

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

The active ingredient in FLOPEN passes into breast milk and there is a possibility that your baby may be affected.

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 any that you get without a prescription from

your pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you are taking this medicine in combination with paracetamol, particularly if you have impaired kidney function.

Some medicines and FLOPEN may interfere with each other. These include:

- probenecid (e.g. Pro-Cid), a medicine commonly used to treat gout
- oral contraceptive pills, medicines used for contraception

You should use other birth control methods while you are taking FLOPEN.

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 this medicine.

How to take FLOPEN

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Usual Adult Dose

250 mg every 6 hours

Usual Child Dose

2 to 10 years: half of the adult dose

Under 2 years: quarter of the adult dose

How to take it

Swallow the capsules whole with a full glass of water.

When to take it

Take your medicine 30 minutes to 1 hour before food.

Food can interfere with the absorption of FLOPEN.

How long to take it

Continue taking your medicine until you finish the pack or for as long as your doctor tells you.

It is important to keep taking your medicine even if you feel well.

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 your medicine 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 to take your medicine, ask your pharmacist for some hints.

If you take 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 the 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.

Symptoms of an overdose may include diarrhoea and nausea.

While you are using FLOPEN

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking FLOPEN.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

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

If you develop yellow eyes or skin (jaundice) whilst or soon after taking FLOPEN tell your doctor immediately. Do this even if it occurs several weeks after you have stopped taking FLOPEN.

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

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

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, or get vaginal itching or discharge, tell your doctor.

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.

If you get severe skin reactions with painful red areas, large blisters, peeling of skin layers; fever, chills, aching muscles, feeling unwell (signs of drug reaction with eosinophilia

and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP), Stevens-Johnson Syndrome or toxic epidermal necrolysis). Stop taking this medicine immediately and tell your doctor.

If you are taking FLOPEN 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 must not do

Do not take any medicine for diarrhoea without first checking with your doctor or a pharmacist.

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

Do not give your medicine to anyone else, even if they have the same condition as you.

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.

Things to be careful of

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

Things to be aware of

FLOPEN can cause jaundice (yellowing of skin and/or eyes) and severe liver disease.

This is more frequent in older patients, particularly those over 55 years of age, and those who take the medicine for more than 14 days.

Immediately contact your doctor if you notice any yellowing of your eyes or skin.

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 a bacterial infection, but it may have unwanted side effects in a few people. All medicines can 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.

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

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

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

- nausea
- vomiting or an upset stomach
- diarrhoea
- a mild rash
- oral thrush - white, furry sore tongue and mouth
- vaginal thrush - sore and itchy vagina and/or discharge

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- watery and severe diarrhoea, which may also be bloody
- severe stomach cramps
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- 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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

If any of the following happen, stop taking FLOPEN and tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- 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

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

After stopping FLOPEN

Tell your doctor if your skin and/or eyes have turned yellow (jaundice) whilst or soon after you finish 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:

- watery and severe diarrhoea, which may also be bloody
- severe abdominal cramps or stomach cramps
- fever, in combination with one or both of the above

These are rare but serious side effects. FLOPEN can change the bacteria (which are normally present in the bowel and are harmless) to multiply and therefore can cause the above symptoms. You may need urgent medical attention.

After using FLOPEN

Storage

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

If you take capsules out of the pack they may not keep well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store FLOPEN 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 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

FLOPEN contains trace amounts of sulfites.

Distributor

FLOPEN is distributed in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000

www.mylan.com.au

This leaflet was prepared in June 2020.

250 mg capsules: AUST R 209367

500 mg capsules: AUST R 209368

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Product description

What it looks like

FLOPEN 250 mg capsules are blue and marked "F250" in white.

FLOPEN 500 mg capsules are blue and marked "F500" in white.

Both strengths are available in packs of 24.

Ingredients

FLOPEN contains 250 mg or 500 mg of flucloxacillin as the active ingredient.

The capsules also contain the following inactive ingredients:

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