

FLOPEN[®] VIATRIS

flucloxacillin (as sodium monohydrate)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about FLOPEN VIATRIS. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking FLOPEN VIATRIS against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What FLOPEN VIATRIS is used for

FLOPEN VIATRIS contains the active ingredient flucloxacillin.

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

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

FLOPEN VIATRIS 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 VIATRIS for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

Before you take FLOPEN VIATRIS

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 VIATRIS 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 VIATRIS 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 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 VIATRIS 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 VIATRIS.

Taking other medicines

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.

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 VIATRIS 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 VIATRIS.

- These medicines may be affected by FLOPEN VIATRIS 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 VIATRIS

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 VIATRIS.

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

If you are not sure what to do, ask 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 you or anyone else may have taken too much FLOPEN VIATRIS. 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 taking FLOPEN VIATRIS

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking FLOPEN VIATRIS.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking FLOPEN VIATRIS.

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

Tell your doctor immediately, if your symptoms 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 VIATRIS tell your doctor immediately. Do this even if it occurs several weeks after you have stopped taking FLOPEN VIATRIS.

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 FLOPEN VIATRIS.

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 FLOPEN VIATRIS, 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 FLOPEN VIATRIS allows fungi to grow and the above symptoms to occur. FLOPEN

VIATRIS 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 VIATRIS 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 pharmacist.

Do not use FLOPEN VIATRIS to treat any other conditions unless your doctor tells you to.

Do not give FLOPEN VIATRIS 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 VIATRIS affects you.

Things to be aware of

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

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 VIATRIS.

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment 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 vaginal discharge).

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

- 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 VIATRIS 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 VIATRIS

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

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 VIATRIS:

- 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 VIATRIS can change the bacteria (which are normally present in the bowel and are harmless) to multiply and therefore cause the above symptoms. You may need urgent medical attention.

After using FLOPEN VIATRIS

Storage

Keep FLOPEN VIATRIS 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.

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

Do not keep FLOPEN VIATRIS or any other medicine in the bathroom or near a sink.

Do not leave FLOPEN VIATRIS in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking FLOPEN VIATRIS, or your capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

FLOPEN VIATRIS comes in two strengths: FLOPEN VIATRIS 250 and FLOPEN VIATRIS 500.

Both are yellow and black capsules.

Each pack contains 24 capsules.

Ingredients

The active ingredient in FLOPEN VIATRIS is flucloxacillin (as flucloxacillin sodium monohydrate).

- each FLOPEN VIATRIS 250 capsule contains 250 mg of flucloxacillin (as sodium monohydrate)
- each FLOPEN VIATRIS 500 capsule contains 500 mg of flucloxacillin (as sodium monohydrate).

The capsules also contain:

- povidone
- purified talc
- sodium starch glycollate
- microcrystalline cellulose
- magnesium stearate

The 250 mg capsules also contain yellow Opaque size 2 (PI 12364).

The 500 mg capsules also contain iron oxide yellow, iron oxide red, brilliant blue FCF, titanium dioxide, gelatin and purified water.

Sponsor

FLOPEN VIATRIS is sponsored by:

Alphapharm Pty Ltd trading as Viatris

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Millers Point NSW 2000

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Phone: 1800 274 276

Australian Registration Numbers:

AUST R: 387418 FLOPEN VIATRIS 250 FLUCLOXACILLIN 250 mg (as sodium) capsule

AUST R: 387419 FLOPEN VIATRIS 500 FLUCLOXACILLIN 500 mg (as sodium) capsule

FLOPEN® is a Viatris company trade mark

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