FLOPEN® VIATRIS

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking FLOPEN VIATRIS?

FLOPEN VIATRIS contains the active ingredient flucloxacillin (as sodium monohydrate). FLOPEN VIATRIS is used to treat infections in different parts of the body caused by bacteria.
For more information, see Section 1. Why am I taking FLOPEN VIATRIS? in the full CMI.

2. What should I know before I take FLOPEN VIATRIS?

Do not take if you have ever had an allergic reaction to FLOPEN VIATRIS 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 take FLOPEN VIATRIS? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FLOPEN VIATRIS 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 take FLOPEN VIATRIS?

- Usual adult dose: 250 mg every 6 hours.
- Usual child dose: 2 to 10 years: half of the adult dose.
- Usual child dose: under 2 years: quarter of the adult dose.
- Take FLOPEN VIATRIS 30 minutes to 1 hour before food.

More instructions can be found in Section 4. How do I take FLOPEN VIATRIS? in the full CMI.

5. What should I know while taking FLOPEN VIATRIS?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking FLOPEN VIATRIS. • 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.
Things you should not do	• Do not take any medicine for diarrhoea without first checking with your doctor or pharmacist. • Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how FLOPEN VIATRIS affects you.
Looking after your medicine	• Keep your capsules in a cool dry place where the temperature stays below 25°C. • Keep it where young children cannot reach it.

For more information, see Section 5. What should I know while taking FLOPEN VIATRIS? in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist if you have any of these: 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). **Stop taking FLOPEN VIATRIS and tell your doctor immediately, or go to Accident and Emergency at the nearest hospital if you notice any of these:** 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 immediately, or go straight to the Emergency Department at your nearest hospital if you notice any of these:** 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.
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.

FLOPEN® VIATRIS

Active ingredient(s): *flucloxacillin (as sodium monohydrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking FLOPEN VIATRIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking FLOPEN VIATRIS.**

Where to find information in this leaflet:

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

1. Why am I taking FLOPEN VIATRIS?

FLOPEN VIATRIS contains the active ingredient flucloxacillin (as sodium monohydrate).

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.

2. What should I know before I take FLOPEN VIATRIS?

Warnings

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

Do not take FLOPEN VIATRIS if:

- you are allergic 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

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

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- 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
- take any medicines for any other conditions
- are pregnant or plan to become pregnant or are breast-feeding.

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 intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

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 and FLOPEN VIATRIS may interfere with each other. These include:

- probenecid, 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.
- methotrexate, a medicine used to treat inflammatory conditions, including severe psoriasis and active rheumatoid arthritis
- warfarin, a medicine used to prevent blood clotting
- voriconazole and posaconazole, medicines used to treat serious fungal or yeast infections
- paracetamol, a medicine used to treat fever and mild to moderate pain
- tacrolimus, a medicine used to prevent organ rejection in transplant patients.

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

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.

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

4. How do I take FLOPEN VIATRIS?

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
- Follow the instructions provided when FLOPEN VIATRIS was prescribed, including the number of days it should be taken.
- 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.

When to take FLOPEN VIATRIS

- FLOPEN VIATRIS should be taken 30 minutes to 1 hour before food.

  Food can interfere with the absorption of FLOPEN VIATRIS.

How to take FLOPEN VIATRIS

- Swallow the capsules whole with a full glass of water.

How long to take FLOPEN VIATRIS

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 FLOPEN VIATRIS

FLOPEN VIATRIS should be taken regularly at the same time each day.

If you miss your dose at the usual time and 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 FLOPEN VIATRIS

If you think that you or anyone else may have taken too much FLOPEN VIATRIS, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 taking FLOPEN VIATRIS?

Things you should do

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

Call your doctor straight away if you:

- become pregnant while taking this medicine.
- notice your symptoms do not improve within a few days, or if they become worse.
- develop yellow eyes or skin (jaundice) whilst or soon after taking FLOPEN VIATRIS.

  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.

- get severe diarrhoea.

  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.

- get severe skin reactions with painful red areas, large blisters, peeling of skin layers; fever, chills, aching muscles, feeling unwell. Stop taking this medicine immediately.

Things you should not do

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

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

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

Do not take this medicine after the expiry date.

6. Are there any 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

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
• 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 or pharmacist if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• 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.	**Stop taking FLOPEN VIATRIS and tell your doctor immediately, or go to Accident and**

Serious side effects	What to do
	Emergency at the nearest hospital if you notice any of these serious side effects.

Very serious side effects

Very serious side effects	What to do
• 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	**Tell your doctor immediately, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.** **You may need urgent medical attention or hospitalisation.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may 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.

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 FLOPEN VIATRIS contains

Active ingredient (main ingredient)	flucloxacillin sodium monohydrate 250 mg or 500 mg per capsule
Other ingredients (inactive ingredients)	• povidone • purified talc • sodium starch glycollate • microcrystalline cellulose • magnesium stearate • iron oxide red • iron oxide yellow • titanium dioxide • brilliant blue FCF • gelatin
Potential allergens	trace amounts of sulfites

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

What FLOPEN VIATRIS looks like

FLOPEN VIATRIS 250 mg is a Size 2 capsule with yellow body and black cap. (AUST R 387418)

FLOPEN VIATRIS 500 mg is a Size 0 capsule with yellow body and black cap. (AUST R 387419)

Available in blister packs of 24 capsules.

Who distributes FLOPEN VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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