

CIPLA FOSFOMYCIN

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using CIPLA FOSFOMYCIN?

CIPLA FOSFOMYCIN contains the active ingredient Fosfomycin trometamol. CIPLA FOSFOMYCIN is only used to treat uncomplicated infections of the bladder in females. It works by killing bacteria which can cause infections.

For more information, see Section [1. Why am I being treated with CIPLA FOSFOMYCIN?](#) in the full CMI.

2. What should I know before I use CIPLA FOSFOMYCIN?

Do not use if you have ever had an allergic reaction to fosfomycin trometamol 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 use CIPLA FOSFOMYCIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CIPLA FOSFOMYCIN 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 use CIPLA FOSFOMYCIN?

- The recommended dose is one sachet of CIPLA FOSFOMYCIN, given once, as a single dose.
- Dissolve the content of one sachet in a glass of cold water and drink immediately (do not use hot water).

More instructions can be found in Section [4. How do I use CIPLA FOSFOMYCIN?](#) in the full CMI.

5. What should I know while using CIPLA FOSFOMYCIN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using CIPLA FOSFOMYCIN.• Tell your doctor if you have or have had any of the following medical conditions:<ul style="list-style-type: none">– an intolerance to some sugars– previously had diarrhoea after taking any antibiotics– kidney problems, but your creatinine clearance is above 10 ml/min.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not take CIPLA FOSFOMYCIN 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.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how CIPLA FOSFOMYCIN affects you.• This medicine may cause dizziness in some people.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using CIPLA FOSFOMYCIN?](#) in the full CMI.

6. Are there any side effects?

Side effects include headache, dizziness, diarrhoea, nausea, vomiting, indigestion, infection of the female genital organs with symptoms like inflammation, irritation, itching, abdominal pain, rash, urticaria and pruritus.

Serious side effects may include anaphylactic shock, symptoms include a sudden onset of rash, itching or hives on the skin and or shortness of breath, wheezing or difficulty in breathing, swelling of the face, lips, tongue or throat with breathing difficulties, mild to severe abdominal cramps, bloody stools, diarrhoea and/or fever may mean that you have an infection of the large intestine.

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.

CIPLA FOSFOMYCIN

Active ingredient(s): *Fosfomicin trometamol*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I using CIPLA FOSFOMYCIN?](#)
- [2. What should I know before I use CIPLA FOSFOMYCIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use CIPLA FOSFOMYCIN?](#)
- [5. What should I know while using CIPLA FOSFOMYCIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using CIPLA FOSFOMYCIN?

CIPLA FOSFOMYCIN contains the active ingredient fosfomicin trometamol and it belongs to a group of medicines called antibiotics.

CIPLA FOSFOMYCIN is only used to treat uncomplicated infections of the bladder in females. It works by killing bacteria which can cause infections. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

CIPLA FOSFOMYCIN is not addictive.

It is available only with a doctor's prescription.

2. What should I know before I use CIPLA FOSFOMYCIN?

Warnings

Do not take CIPLA FOSFOMYCIN if:

- you are allergic to fosfomicin trometamol, or any of the ingredients listed at the end of this leaflet.

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

Do not give this medicine to a child under the age of 12 years.

Use is not recommended if you have severe kidney problems (creatinine clearance below 10 ml/min).

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

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?](#)

Before you take CIPLA FOSFOMYCIN:

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:

- an intolerance to some sugars
- previously had diarrhoea after taking any antibiotics
- kidney problems, but your creatinine clearance is above 10 ml/min.

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.

Children

Safety and effectiveness in children younger than 12 years have not been established.

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.

If you are pregnant, the active ingredient in CIPLA FOSFOMYCIN can cross the placenta and CIPLA FOSFOMYCIN can pass into the foetus. There is a possibility that your baby may be affected.

The active ingredient in CIPLA FOSFOMYCIN 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 him/her before you start taking CIPLA FOSFOMYCIN.

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 may interfere with CIPLA FOSFOMYCIN and affect each other. These include:

- metoclopramide or other drugs that increase the movement of food through the stomach and intestines, because they may reduce the uptake of fosfomycin trometamol by your body.
- anticoagulants, as their ability to prevent your blood from clotting might be altered by fosfomycin trometamol and other antibiotics.
- urinary alkalinisers can alter the acidity of the urine and may interfere with how fosfomycin works.

These medicines may be affected by CIPLA FOSFOMYCIN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while 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 CIPLA FOSFOMYCIN.

4. How do I use CIPLA FOSFOMYCIN?

How much to take

- The recommended dose is one sachet of CIPLA FOSFOMYCIN, given once, as a single dose.
- Dissolve the content of one sachet in a glass of cold water and drink immediately (do not use hot water).
- 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 CIPLA FOSFOMYCIN

- CIPLA FOSFOMYCIN be used on an empty stomach, (2-3 hours before or 2-3 hours after a meal), preferably before going to bed and after emptying the bladder.
- Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you forget to use CIPLA FOSFOMYCIN

CIPLA FOSFOMYCIN should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose you missed.

If you use too much CIPLA FOSFOMYCIN

If you think that you have used too much CIPLA FOSFOMYCIN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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.

5. What should I know while using CIPLA FOSFOMYCIN?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking CIPLA FOSFOMYCIN.
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
- It may affect other medicines used during surgery.
- If you become pregnant while taking this medicine, tell your doctor immediately.
- If you are about to have any blood tests, tell your doctor that you are taking this medicine.
- It may interfere with the results of some tests.
- Keep all of your doctor's appointments so that your progress can be checked.

Call your doctor straight away if you:

- Experience anaphylactic shock, a life-threatening type of allergic reaction
- Symptoms include a sudden onset of rash, itching or hives on the skin and or shortness of breath, wheezing or difficulty in breathing swelling of the face, lips, tongue or throat with breathing difficulties (angioedema)
- mild to severe abdominal cramps,
- bloody stools, diarrhoea and/or fever may mean that you have an infection of the large intestine (antibiotic associated colitis).

Remind any doctor, dentist or pharmacist you visit that you are using CIPLA FOSFOMYCIN.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not take CIPLA FOSFOMYCIN 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CIPLA FOSFOMYCIN affects you.

CIPLA FOSFOMYCIN may cause headache or dizziness in some people. If you have experienced this symptom, do not drive, operate machinery or do anything else that could be dangerous.

CIPLA FOSFOMYCIN contains Sucrose

This medicine contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Looking after your medicine

- Keep your sachet in the carton until it is time to take them. If you take the sachet out of the carton they may not keep well.
- Keep your medicine 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 children cannot reach it.

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

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

When to discard your medicine

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.

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

Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date.

6. Are there any side effects?

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.

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
<ul style="list-style-type: none">• headache• dizziness• diarrhoea (if it becomes severe consult your doctor immediately)• nausea, vomiting• indigestion (dyspepsia)• infection of the female genital organs with symptoms like inflammation, irritation, itching (vulvovaginitis)• abdominal pain• rash, urticaria, pruritus	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• anaphylactic shock, a life-threatening type of allergic reaction• Symptoms include a sudden onset of rash, itching or hives on the skin and or shortness of breath, wheezing or difficulty in breathing• swelling of the face, lips, tongue or throat with breathing difficulties (angioedema)• mild to severe abdominal cramps, bloody stools, diarrhoea and/or fever may mean that you have an infection of the large intestine (antibiotic-associated colitis).	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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

This leaflet was prepared in June 2024.

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

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 CIPLA FOSFOMYCIN contains

Active ingredient (main ingredient)	fosfomycin trometamol as the active ingredient, equivalent to 3 g of fosfomycin
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• mandarin flavour,• orange powder flavour,• saccharin,• sucrose (CIPLA FOSFOMYCIN contains 2.213 g of sucrose)
Potential allergens	-

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

What CIPLA FOSFOMYCIN looks like

CIPLA FOSFOMYCIN is presented as white to off-white powder for oral solution in a single use sachet.

Each carton contains 1 sachet which is a 4 ply laminate foil (41 gsm OLB paper/17 gsm PE/ 12 micron aluminum foil/35 gsm PE).

CIPLA FOSFOMYCIN sachet is supplied in an outer cardboard carton, one sachet per carton.

Australian Registration Number

AUST R 389417

Who distributes CIPLA FOSFOMYCIN

Cipla Australia Pty Ltd.,
Level 1 / 132-136 Albert road,
South Melbourne Vic 3205.
drugsafety@cipla.com
Phone: 1800-569-074