

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 MONUROL?

MONUROL contains the active ingredient fosfomycin trometamol. MONUROL is a single dose antibiotic used to treat uncomplicated urinary tract infections in females.

For more information, see Section [1. Why am I taking MONUROL?](#) in the full CMI.

2. What should I know before I take MONUROL?

Do not take 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 take MONUROL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MONUROL 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 MONUROL?

One sachet of MONUROL, dissolved in a glass of cold water and taken on an empty stomach, before bed and after emptying the bladder.

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

5. What should I know while taking MONUROL?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking MONUROL.• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.• 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.
Things you should not do	<ul style="list-style-type: none">• Do not take MONUROL 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">• If you experience dizziness, do not drive, operate machinery or do anything else that could be dangerous.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep your sachet in the carton until it is time to take them.• Store it in a cool dry place away from moisture, heat or sunlight.

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

6. Are there any side effects?

Common side effects: headache, dizziness, diarrhoea (if it becomes severe consult your doctor immediately), nausea, vomiting, indigestion, infection of the female genital organs with symptoms like inflammation, irritation, itching, abdominal pain, rash, urticaria, pruritus. Serious side effects: mild to severe abdominal cramps, bloody stools, diarrhoea and/or fever. Serious signs that you may be having an allergic reaction include swelling of the face, lips, tongue or throat with breathing difficulties.

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.

MONUROL®

Active ingredient: fosfomycin trometamol

Consumer Medicine Information (CMI)

This leaflet provides important information about taking MONUROL. **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 MONUROL.**

Where to find information in this leaflet:

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

1. Why am I taking MONUROL?

MONUROL contains the active ingredient fosfomycin trometamol. Fosfomycin trometamol is an antibiotic that has activity against *E.coli* and *E. faecalis* bacteria.

MONUROL is used to treat uncomplicated urinary tract infections 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.

2. What should I know before I take MONUROL?

Warnings

Do not take MONUROL if:

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

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

Do not give this medicine to a child under the age of 12 years. Safety and effectiveness in children younger than 12 years have not been established.

Use is not recommended if you have severely reduced kidney function (creatinine clearance below 10 ml/min).

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- take any medicines for any other condition.
- Have or have had any other medical conditions such as:
 - o an intolerance to some sugars
 - o diarrhoea after taking any antibiotics
 - o reduced kidney function, but your creatinine clearance is above 10 ml/min.

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.

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

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

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 MONUROL may interfere with 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 alkalisers (e.g. Ural®) or acidic drinks (e.g. cranberry juice) can alter the acidity of the urine and may interfere with how MONUROL works. Therefore use of MONUROL with these agents is not recommended.

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

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

4. How do I take MONUROL?

How much to take

- The recommended dose is one sachet of MONUROL, given once, as a single dose dissolved in a glass of cold water.
- Follow the instructions provided when MONUROL was prescribed.

When to take MONUROL

- Take your medicine 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. MONUROL works most efficiently under these conditions.

How to take MONUROL

- Dissolve the content of one sachet in a glass of water and drink immediately (do not use hot water).

If you forget to take MONUROL

If you forget to take it after filling your prescription, take it the very next day.

If you take too much MONUROL

If you think that you have taken too much MONUROL, 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 taking MONUROL?

Things you should do:

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

Remind any doctor, dentist or pharmacist you visit that you are taking MONUROL.

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.

Things you should not do:

- Do not take MONUROL 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 MONUROL affects you.

MONUROL may cause dizziness in some people

If you have experienced this symptom, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your sachet in the carton until it is time to take it. If you take the sachet out of the carton it may not keep well.

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 windowsills.

Keep it where young children cannot reach it.

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?

All medicines can have side effects. If you do experience any side effects with MONUROL, 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">• mild to severe abdominal cramps, bloody stools, diarrhoea	Call your doctor straight

Serious side effects	What to do
<p>and/or fever may mean that you have an infection of the large intestine (antibiotic-associated colitis)</p> <p>Serious signs of an allergic reaction to MONUROL:</p> <ul style="list-style-type: none"> • 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) 	<p>away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects</p>

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.

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 MONUROL contains

Active ingredient (main ingredient)	5.631 g of fosfomycin trometamol as the active ingredient, equivalent to 3 g of fosfomycin
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • tangerine flavour • orange flavour • saccharin • sucrose (MONUROL contains 2.213 g of sucrose).
Potential allergens	This medicine does not contain lactose, gluten, tartrazine or any other azo dyes.

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

What MONUROL looks like

MONUROL is presented as white granules for oral solution in a single use sachet.

The sachet is a four-layer laminate, comprising of: paper/polyethylene/aluminium/ polyethylene.

MONUROL sachet is supplied in an outer cardboard carton, one sachet per carton. (Aust R 278658).

Who distributes MONUROL?

Australia

Mayne Pharma International Pty Ltd
1538 Main North Road
Salisbury South, SA 5106

This leaflet was prepared in May 2025.