

MONUROL®

Fosfomycin trometamol

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MONUROL. 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 MONUROL 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 MONUROL is used for

MONUROL contains the active ingredient fosfomycin trometamol and it belongs to a group of medicines called antibiotics.

MONUROL 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.

MONUROL is not addictive.

It is available only with a doctor's prescription.

Before you take MONUROL

When you must not take it

Do not take MONUROL if you:

- are allergic to fosfomycin trometamol or any of the other ingredients listed at the end of this leaflet
- have severe kidney problems (creatinine clearance below 10 ml/min)
- are undergoing haemodialysis.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

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.

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 it 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:

- 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.

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.

If you have not told your doctor about any of the above, tell him/her before you start taking MONUROL.

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.

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.

These medicines 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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take MONUROL

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

The recommended dose is one sachet of MONUROL, given once, as a single dose.

How to take it

Dissolve the content of one sachet in a glass of water and drink immediately.

MONUROL should not be taken in its dry form. Always mix MONUROL with water before ingesting. Do not use hot water.

MONUROL should be taken immediately after dissolving in water.

When to take it

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.

How long to take it

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 take too much (overdose)

If you accidentally take more than your prescribed dose, contact your doctor or pharmacist.

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 MONUROL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include changes in hearing and taste perception.

While you are taking MONUROL

Things you must do

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

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.

Things you must 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.

Things to be careful of

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

This medicine may cause dizziness in some people. If you have experience this symptom, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MONUROL.

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 the following lists of 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:

- 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)
- tingling of the skin mouth, cheeks and/or tongue (paraesthesias)
- temporary reduced, altered or metallic taste sensation
- abdominal pain
- rash, urticaria, pruritus
- fatigue
- asthma with symptoms such as wheezing, shortness of breath, coughing and chest tightness
- low blood pressure (hypotension).

Tell your doctor as soon as possible if you notice any of the following:

- 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)
- faster heart beat (tachycardia)
- 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).

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 taking MONUROL

Storage

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.

Do not store MONUROL 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 the 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.

Product description

What it 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.

Ingredients

MONUROL contains 5.631 g of fosfomycin trometamol as the active ingredient, equivalent to 3 g of fosfomycin.

- tangerine flavour
- orange juice flavour
- saccharin
- sucrose (MONUROL contains 2.213 g of sucrose).

This medicine does not contain lactose, gluten, tartrazine or any other azo dyes.

Supplier

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