

Monuril 3g

Granules for oral solution
fosfomycin



Package leaflet: Information for the user

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

- What in this leaflet**
1. What Monuril is and what it is used for
 2. What you need to know before you take Monuril
 3. How to take Monuril
 4. Possible side effects
 5. How to store Monuril
 6. Contents of the pack and other information.

1. What Monuril is and what it is used for

Monuril contains the active substance fosfomycin trometamol. Fosfomycin trometamol is an antibiotic that works by killing bacteria which can cause infections.

Monuril is used to treat or prevent uncomplicated infections of the bladder.

Monuril is not suitable for the treatment of children below 12 years of age.

2. What you need to know before you take Monuril

- Do not take Monuril if you:**
- are allergic to fosfomycin trometamol or any of the other ingredients of this medicine (listed in section 6)
 - have severe kidney problems (creatinine clearance below 10 ml/min)
 - are undergoing haemodialysis.

- Warnings and precautions**
- Talk to your doctor or pharmacist before taking Monuril if you have:
- an allergic reaction during treatment (see section 4)
 - an intolerance to some sugars (see end of section 2)
 - previously had diarrhoea after taking any other antibiotics
 - kidney problems, but your creatinine clearance is above 10 ml/min.

Children and adolescents

Do not give this medicine to children less than 12 years of age, as its safety and efficacy have not been established in this age group.

- Other medicines and Monuril**
- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
- This is especially important if you are taking:
- **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.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnant women may be able to use fosfomycin trometamol if it is considered necessary.

Breast-feeding mothers can take a single oral dose of this medicine.

There are no known effects of fosfomycin trometamol on fertility.

Driving and using machines

You may experience side effects such as dizziness which may affect your ability to drive or use machines.

Monuril contains 2.213 g of sucrose: if you have been told by your doctor that you have intolerance to some sugars, ask your doctor for advice before taking this product.

3. How to take Monuril

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended doses are:
- for acute uncomplicated bladder infections, 1 sachet of Monuril 3 g, once
 - for prevention of infection in surgery and diagnostic procedures, 1 sachet of Monuril 3 g, 3 hours before surgery. You may be given a further sachet of 3 g 24 hours after surgery.

Use in children and adolescents

This medicine should not be used in children less than 12 years of age.

Method of administration

Take this medicine by mouth, on an empty stomach (2-3 hours before or 2-3 hours after a meal), preferably before going to bed after emptying the bladder.

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

If you take more Monuril than you should

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

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If you forget to take Monuril

If you forget to take a dose, take one as soon as you remember.
Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

While taking Monuril, if you develop any of the following symptoms **you should contact your doctor immediately**:

- anaphylactic shock, a life threatening type of **allergic reaction** (*the frequency is unknown*). 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) (*the frequency is unknown*)
- **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) (*the frequency is unknown*).

Other side effects

If any of the following side effects occur, contact your doctor as soon as possible:

Common (may affect up to 1 in 10 people):

- headache
- dizziness
- diarrhoea - if it becomes severe consult your doctor immediately
- nausea
- infection of the female genital organs with symptoms like inflammation, irritation, itching (vulvovaginitis).

Uncommon (may affect up to 1 in 100 people):

- vomiting
- abdominal pain
- rash
- urticaria
- pruritus

Unknown frequency:

- allergic reactions.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Monuril

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after <EXP>. The expiry date refers to the last day of that month.

Store away from direct sunlight.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Monuril contains

- The active substance is fosfomycin. Each sachet contains 5.631 g of fosfomycin trometamol, equivalent to 3 g of fosfomycin
- the other ingredients are mandarin flavour, orange flavour, saccharin, sucrose (see section 2 for information on sucrose).

What Monuril looks like and contents of the pack

White granules for oral solution in a single dose sachet.

Sachets are four layers laminate of: paper/polyethylene/aluminium/polyethylene.

Monuril is available in packs containing:

- 1 sachet of 8 g of granules (3 g fosfomycin)
 - 2 sachets of 8 g of granules (3 g fosfomycin)
 - 5 sachets of 8 g of granules (3 g fosfomycin).
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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