

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S4

**MONURIL, 3 g, granules**

**Fosfomicin trometamol**

**Contains sugar (sucrose): 2,213 g per sachet.**

**Contains sweetener (saccharin): 0,016 g per sachet.**

### Read all of this leaflet carefully before you start taking MONURIL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MONURIL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### What is 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 is a broad-spectrum bactericidal antibiotic.

MONURIL is used to treat urinary tract infections such as bladder infections in women and female

children over the age of five years.

MONURIL is used to prevent infections in men receiving urinary surgical procedures.

## **2. What you need to know before you take MONURIL**

### **Do not take MONURIL:**

- if you are hypersensitive (allergic) to fosfomycin trometamol or any of the other ingredients of MONURIL (listed in section 6).
- if you have kidney disease: The effects of fosfomycin may be increased because of slower removal from the body.

### **Warnings and precautions**

#### **Take special care with MONURIL:**

##### **Children**

Safety and efficacy in children under the age of five years has not yet been established.

##### **Other medicines and MONURIL**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking metoclopramide (used to treat nausea (feeling sick) and vomiting (being sick)).

##### **MONURIL with food and drink**

MONURIL should be taken at least two hours prior to your next meal. Food delays and reduces absorption of MONURIL.

##### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking MONURIL. Do not take MONURIL during pregnancy or breastfeeding.

**Driving and using machines:**

MONURIL may cause dizziness which can affect your ability to drive a vehicle and use machines. It is not always possible to predict to what extent MONURIL may interfere with your daily activities. Do not engage in the above activities until you know how MONURIL affects you.

**MONURIL contains sucrose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking MONURIL.

**3. How to take MONURIL**

Do not share medicines prescribed for you with any other person. Always take MONURIL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for uncomplicated urinary tract infections in women, including the elderly up to seventy-five years, is a single 3 g dose.

The recommended dose to prevent a bacterial infection before a urinary surgical procedure in adult men, including the elderly, is two doses of 3 g. The first dose should be taken three hours before surgery. The second dose should be taken twenty-four hours after surgery.

Dissolve MONURIL in water and drink it as soon as it has been dissolved. Take MONURIL at least two hours before your next meal.

If you have the impression that the effect of MONURIL is too strong or too weak, tell your doctor or pharmacist.

**If you take more MONURIL than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

#### **4. Possible side effects**

MONURIL can have side effects.

Not all side effects reported for MONURIL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MONURIL, please consult your health care provider for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to MONURIL. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- headache, dizziness,
- sore throat, runny or stuff nose,
- diarrhoea, nausea (feeling sick),
- stomach pain, heartburn,
- skin rash,
- back pain,
- vaginal discharge,
- painful periods (menstruation)
- pain, weakness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

#### **Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of MONURIL.

## **5. How to store MONURIL**

- Store at or below 30 °C.
- Store in the original packaging until required for use.
- Store all medicines out of reach of children.

## **6. Contents of the pack and other information**

### **What MONURIL contains**

The active substance is fosfomycin trometamol equivalent to fosfomycin.

The other ingredients are mandarin flavour, orange flavour, saccharin and sucrose.

### **What MONURIL looks like and contents of the pack**

White granular powder with a characteristic mandarin flavour.

Printed cardboard carton containing one paper-polyethylene-aluminium-polyethylene laminated sachet.

### **Holder of Certificate of Registration**

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**This leaflet was last revised in**

10 May 2022

**Registration number**

550358