PACKAGE LEAFLET: INFORMATION FOR THE USER MONURIL® ADULT (fosfomycin) 3g, granules for oral solution in sachet

Read this entire leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you experience serious side effects, or if you notice side effects not listed in this leaflet, please tell your doctor or pharmacist.

1. WHAT MONURIL® IS AND WHAT IT IS USED FOR

This medicine is an antibiotic indicated in the treatment of non-complicated acute cystitis (urinary tract infection). The normal dose is one sachet.

2. BEFORE YOU TAKE MONURIL®

Do not take MONURIL® if you are allergic (hypersensitive) to fosfomycin or any of the other ingredients of MONURIL® (see "further information" for a list of all ingredients)

Special warnings:

MONURIL® single dose treatment is not appropriate for complicated cystitis, urinary infections in pregnant women, kidney infections or prostate infections in men. The pain due to the infection may persist for 24 to 48 hours after the administration of MONURIL®. This time lag should not worry you. However, if after this time period the pain

persists, contact your doctor. If your doctor has informed you of an intolerance to certain sugars, contact him/her before taking this medicine.

This medicine contains 2.213g of sucrose per sachet. This medicine should not be used by patients with fructose intolerance, glucose and galactose malabsorption syndrome or sucrase-isomaltase deficiency (rare metabolic diseases).

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Taking other medicines:

In order to avoid possible interactions with other medicinal products, you must always inform your doctor or pharmacist of any other current treatment.

Pregnancy / Breastfeeding

In pregnant women other types of treatments may be preferred in urinary infections. However, its administration during pregnancy does not expose to a risk for the unborn child. It is inadvisable to take this medicine during breastfeeding as fosfomycin passes into breast milk.

ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE BEFORE TAKING ANY MEDICINE.

3. HOW TO TAKE MONURIL®

<u>Dosage</u>

Oral route.

One sachet of MONURIL® as a single dose (on occasion a second dose may be prescribed after 3 days)

Dissolve the contents of a MONURIL® sachet in half a glass of water.

To be taken on an empty stomach. ALWAYS USE AS DIRECTED.

4. POSSIBLE SIDE EFFECTS OF MONURIL®

Like all medicines, MONURIL® may, in certain individuals, give rise to varying degrees of unpleasant effects: nausea, vomiting, diarrhoea, or skin rashes.

These effects disappear on their own and do not require any special treatment.

INFORM YOUR DOCTOR OR PHARMACIST OF ANY UNDESIRABLE AND UNPLEASANT EFFECT NOT MENTIONED IN THIS LEAFLET.

This medicine has been prescribed for you for a specific situation.

5. HOW TO STORE TAKE MONURIL®

Keep out of the reach and sight of children.

Do not use MONURIL® after the expiry date which is stated on the outer packaging. The expiry date refers to the last day of that month.

Store in a cool dry place.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

The active substance is:

Fosfomycin 3g (as trometamol: 5.631g/sachet) Other ingredients are: Saccharin, sucrose, mandarin flavour, orange flavour. This medicine is available as granules for oral solution in a sachet.

HEALTH ADVICE

What you should know about antibiotics:

Antibiotics are effective to fight infections caused by bacteria. They are ineffective against viral infections. Your doctor has decided to prescribe this antibiotic because it is particularly appropriate for your current infection. Bacteria can survive and multiply in spite of the action of an antibiotic. This phenomenon is called resistance; it makes certain antibiotic treatments inactive. Resistance increases with misuse or inappropriate use of antibiotics.

In order to preserve the efficacy of this medicine:

- 1. Only use an antibiotic when your doctor prescribes it
- 2. Strictly follow your prescription
- 3. Do not reuse an antibiotic without medical prescription
- 4. Never give your antibiotic to another person: it may not be appropriate for his/her infection.