PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

UTICIDE, 3 g granules for oral solution

Fosfomycin trometamol

Contains sugar (sucrose) and sweetener (saccharin)

One sachet contains 2,213 g sucrose and 0,016 g saccharin

Read all of this leaflet carefully before you start taking UTICIDE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- UTICIDE 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 UTICIDE is and what it is used for
2. What you need to know before you take UTICIDE
3. How to take UTICIDE
4. Possible side effects
5. How to store UTICIDE
6. Contents of the pack and other information

1. What UTICIDE is and what it is used for

UTICIDE is a broad-spectrum antibiotic that is used in women and adolescent women to treat urinary tract and bladder infections. It is used in adult men to prevent infection from urinary surgery.

2. What you need to know before you take UTICIDE

Do not take UTICIDE:

- if you are hypersensitive (allergic) to fosfomycin or any of the other ingredients of UTICIDE (listed in section 6, “What UTICIDE contains”);
- if you suffer from severe kidney problems;
- if you are undergoing haemodialysis (a procedure used to clean the blood from wastes and extra fluids, when the kidneys are not working).

Warnings and special precautions

Take special care with UTICIDE:

- if you have an allergic reaction on UTICIDE. See section 4, “Possible side effects” for some signs of an allergic reaction. Contact your doctor immediately if you have such symptoms.
- Tell your doctor, pharmacist or nurse before taking UTICIDE if you have previously experienced diarrhoea upon administration of any other antibiotics. UTICIDE may cause severe diarrhoea and inflammation of the bowel in some patients (see section 4).
- Tell your doctor if you have kidney disease. The effects of UTICIDE may be increased because of slower removal from the body.

Children

UTICIDE 3 g is not indicated for children between the ages of 5 and 12 years, as the sachets cannot be divided.

Other medicines and UTICIDE

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

Tell your doctor if you take:

- a medicine called metoclopramide (a medicine to stop you from feeling sick) as this may influence UTICIDE;
- medicines that reduce blood clotting (such as warfarin).

UTICIDE with food and drink

Food delays and reduces the absorption of UTICIDE, resulting in reduced blood and urinary concentrations.

UTICIDE should be taken on an empty stomach at least 2 hours before the next meal, or at least 2 to 3 hours after a meal.

Pregnancy and breastfeeding

Safety has not been established for use in pregnancy. Do not take UTICIDE if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare provider for advice.

Fosfomycin is excreted into human milk. You should not breastfeed your baby if you take UTICIDE, or you should not take UTICIDE if you breastfeed your baby.

Driving and using machines

You may experience side effects such as dizziness which may affect your ability to drive or use machines. Do not drive or use machines if you are affected.

UTICIDE contains sugar (sucrose) and sweetener (saccharin)

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

3. How to take UTICIDE

Do not share medicines prescribed for you with any other person.

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

The usual dose is:

Adult and adolescent women (> 12 years of age):

Only one dose is taken: One 3 g sachet of UTICIDE as a single dose, at least 2 hours before the next meal, on an empty stomach.

Adult men:

Two doses are usually taken:

- One 3 g sachet 3 hours *before* surgery
- One 3 g sachet 24 hours *after* surgery.

Directions for use:

Dissolve the contents of the sachet in a glass of water and drink all the contents immediately.

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

If you take more UTICIDE than you should

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

If you forget to take a dose

If you forget to take the dose, take it as soon as you remember.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking UTICIDE

Women only take a single dose.

For effective prevention of infection, men should take both their doses as directed in section 3, “How to take UTICIDE”.

4. Possible side effects

UTICIDE can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash, itching or hives on the skin;
- abdominal pain, nausea with yellowing of the skin and eyes, which may be due to jaundice or liver failure;
- severe abdominal cramps, bloody stools, rapid heart rate and/or fever. These symptoms may mean that you have an infection of the large intestine (pseudomembranous colitis) or a toxic megacolon (an abnormal dilation of the large intestine).

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- signs of infections, such as a sore throat, vaginal inflammation, or combined vaginal and vulvar inflammation;
- worsening of asthma.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- headache
- dizziness
- runny nose
- diarrhoea
- nausea (feeling sick)
- dyspepsia (heartburn)
- abdominal pain
- back pain
- painful menstruation
- general pain
- abnormal physical weakness

Less frequent side effects

- vomiting
- pain in the eye, vision loss (inflammation of the optic nerve)

Blood tests may show:

- Low white blood cell count
- Low numbers of red blood cells
- Low blood platelet count
- Increase in certain enzymes in the body (aminotransferases, alkaline phosphatase)
- Increase in bilirubin (an orange-yellow pigment formed in the liver).

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 Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/health-products-vigilance/. By reporting side effects, you can help provide more information on the safety of UTICIDE. Reporting can also be done directly to Unicorn Pharmaceuticals at: vigilance@unicornpharma.co.za.

5. How to store UTICIDE

Store all medicines out of reach of children.

Store at room temperature (at or below 25 °C).

Do not store in a bathroom.

Use entire contents immediately once opened.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What UTICIDE contains

The active substance is fosfomycin. Each sachet contains fosfomycin trometamol equivalent to 3 g fosfomycin.

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

What UTICIDE looks like and contents of the pack

The granules for oral solution are white or almost white, without lumps or foreign particles.

UTICIDE is packed in a four layered (surlyn/aluminium/low-density polyethylene/paper) sachet.

1 or 2 sachets are packed into printed cardboard boxes.

Not all packing sizes may be marketed at any one time.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

Corner Searle and Pontac Streets

Woodstock

Cape Town

8001

enquiries@unicornpharm.co.za

This leaflet was last revised in

TBA

Registration number

53/20.1.1/0574