PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

FOMNOS (3 gram powder for oral solution).

Fosfomycin trometamol, equivalent to 3,0 g fosfomycin.

FOMNOS contains sugar (2 193,0 mg sucrose) per sachet.

FOMNOS contains sweetener (16,0 mg saccharin sodium) per sachet.

Read all of this leaflet carefully before you start taking FOMNOS

- 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.
- FOMNOS 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 FOMNOS is and what it is used for.

2. What you need to know before you take FOMNOS.

3. How to take FOMNOS.

4. Possible side effects.

5. How to store FOMNOS.

6. Contents of the pack and other information.

1. What FOMNOS is and what it is used for

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

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

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

2. What you need to know before you take FOMNOS

Do not take FOMNOS if you:

- Are hypersensitive (allergic) to fosfomycin or any of the other ingredients of FOMNOS (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 FOMNOS if you have:

- An allergic reaction during treatment (see section 4).

- Persistent infections of the bladder.
- Previously had diarrhoea after taking any other antibiotics.

Conditions you need to look out for

FOMNOS can cause serious side effects. These include allergic reactions and an inflammation of the large intestine. You must look out for certain symptoms while you are taking this medicine, to reduce the risk of any problems. See “Serious side effects” in Section 4.

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 FOMNOS

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

If you are taking other medicines, FOMNOS may affect how well they work or may cause side effects.

If you are taking any of the following medicines, check with your doctor or pharmacist before taking FOMNOS:

- Metoclopramide or other medicinal products that increase the movement of food through the stomach and intestines, because they may reduce the uptake of fosfomycin by your body.
- Anticoagulants, as their ability to prevent your blood from clotting might be altered by fosfomycin and other antibiotics.

FOMNOS with food and drink

Food may delay the absorption of fosfomycin. Therefore, FOMNOS should be taken on an empty stomach (2 to 3 hours before or 2 to 3 hours after a meal).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding or think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Breastfeeding mothers should not be given this medicine.

There are no known effects of fosfomycin on fertility.

Driving and using machines

You may feel dizzy when taking FOMNOS. If this happens, it may be dangerous to do things such as drive or use machines.

This medicine can affect your ability to drive. Do not drive or use machines whilst taking FOMNOS until you know how FOMNOS affects you.

Important information about some of the ingredients of FOMNOS

FOMNOS contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

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

3. How to take FOMNOS

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

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

The usual doses are

- For acute uncomplicated bladder infections, 1 sachet of FOMNOS, once.
- For prevention of infection in surgery and diagnostic procedures, 1 sachet of FOMNOS, 3 hours before surgery and 1 sachet of FOMNOS 24 hours after surgery.

The contents of a sachet should be dissolved in 50 to 75 mℓ of water and taken immediately after its preparation.

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

If you take more FOMNOS than you should

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

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

If you forget to take FOMNOS

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

4. Possible side effects

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

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

Serious side effects

While taking FOMNOS, if you develop any of the following symptoms you should stop taking the medicine and 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*).
- Moderate to severe diarrhoea, abdominal cramps, bloody stools and/or fever may mean that you have an infection of the large intestine (antibiotic-associated colitis) (*the frequency is unknown*). Do not take medicines against diarrhoea that inhibit the bowel movements (antiperistaltics).

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

Tell your doctor if you notice any of the following:

Frequent:

- 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).
- Heartburn.
- Indigestion.
- Abdominal pain.
- Inflammation of the vagina that can result in discharge, itching and pain (vaginitis).
- Painful menstrual periods.
- Pain such as back pain.
- Sore throat.
- Runny or stuffy nose.
- Feeling of weakness.

Less frequent:

- Vomiting.
- Rash.
- Pinkish, itchy swellings on the skin also called hives or nettle rash (urticaria).
- Itching (pruritus).

Frequency unknown:

- Allergic reactions.

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 or pharmacist. 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 FOMNOS.

Suspected adverse reactions can also be reported directly to the HCR (Holder of Certificate of Registration) via Patientsafety.sacg@novartis.com.

5. How to store FOMNOS

- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Store at or below 25 °C.
- Keep the sachet in the outer carton until required for use.
- Do not use after the expiry date stated on the label/carton.
- Return all unused medicines 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 FOMNOS contains

Each single-dose sachet contains 5 631,0 mg fosfomycin trometamol, equivalent to 3,0 g fosfomycin.

Contains sugar (2 193,0 mg sucrose).

Contains sweetener (16,0 mg saccharin sodium).

List of excipients

- Orange flavour: arabic gum (E414), BHA E320, dextrose monohydrate, ethyl butyrate, ethyl hexanoate, isoamyl acetate, isoamyl hexanoate, linalol, maltodextrine, natural citral 96 %, nerol, natural lemon essential oil 0,54 % and natural orange essential oil 3,06 %.
- Sucrose.
- Saccharin sodium.

What FOMNOS looks like and contents of the pack

Powder for oral solution.

Sachets containing white or off-white powder with orange flavour.

Sachets are made of a high barrier laminate (Paper/Low Density Polyethylene/Aluminium/Low Density Polyethylene) and supplied in an outer cardboard carton containing 1 sachet.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

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Access to the corresponding Professional Information

Not applicable.

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