1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

TRACTINFECT 3 g powder

Fosfomycin trometamol

Contains sugar: Sucrose 2,193 g

Contains sweetener: Saccharin sodium 16 mg

Read all of this leaflet carefully before you start taking TRACTINFECT

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

1. What TRACTINFECT is and what it is used for

TRACTINFECT belongs to a group of medicines called antibiotics. It works by killing bacteria, which can cause infections.

TRACTINFECT is used to treat infections of the bladder in women 12 years and older.

TRACTINFECT is used to prevent infections in diagnostic and surgical transurethral procedures and transrectal prostate biopsy in adult men.

2. What you need to know before you take TRACTINFECT

Do not take TRACTINFECT:

- if you are hypersensitive (allergic) to fosfomycin trometamol or any of the other ingredients of TRACTINFECT (listed in section 6).
- if you suffer from kidney problems,
- if you are undergoing haemodialysis (a procedure used to clean the blood by filtering out wastes and extra fluids, when the kidneys are not functioning).

Warnings and precautions

Take special care with TRACTINFECT:

- If you have previously experienced diarrhoea after taking any other antibiotics. Tell your doctor as you may develop serious diarrhoea during or after using TRACTINFECT and need to be treated immediately.
- If you have persistent infections of the bladder.
- If you are a male patient with a bladder infection, as this is usually considered a complicated urinary tract infection and you should be in contact with your treating doctor.
- If you are elderly.

Children (under 12 years of age)

Do not give TRACTINFECT to children younger than 12 years of age.

Other medicines and TRACTINFECT

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

Tell your doctor if you are taking any of the following:

- Metoclopramide: a medicine to stop you from feeling nauseous or from vomiting. If you take them together TRACTINFECT may be less effective.
- Anticoagulants: medicines used to prevent blood clotting such as warfarin.

TRACTINFECT with food and drink

Do not take TRACTINFECT with food (see section 3).

Food may delay the absorption of TRACTINFECT, it is therefore preferable to take TRACTINFECT on an empty stomach or about 2 to 3 hours after meals.

Pregnancy, breastfeeding and fertility

You should not breastfeed while you are taking TRACTINFECT.

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 healthcare provider for advice before taking this medicine.

Driving and using machines

You may experience side effects such as dizziness or fatigue which may affect your ability to drive or use machines. Do not drive or use machines until you know how TRACTINFECT affects you.

TRACTINFECT contains the sugar, sucrose

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

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take TRACTINFECT.

3. How to take TRACTINFECT

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

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

The usual dose in women over the age of 12 years and elderly patients is one sachet (3 g) of TRACTINFECT as a single dose.

The usual dose in adult and elderly male patients, scheduled for transurethral surgical and diagnostic procedures or for transrectal prostate biopsy 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.

Use in children and adolescents

TRACTINFECT should not be used in children younger than 12 years of age.

Route and methods of administration

TRACTINFECT should be taken by mouth. Take TRACTINFECT on an empty stomach, at least two hours prior to the next meal or preferably before bedtime, after emptying the bladder. The contents of the sachet should be dissolved in half a glass of water.

Your doctor will tell you how long your treatment with TRACTINFECT will last. If you have the impression that the effect of TRACTINFECT is too strong or too weak, tell your doctor or pharmacist.

If you take more TRACTINFECT 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.

You may experience loss of balance, difficulty hearing or changes in the way you taste things. Your doctor will treat this as necessary.

If you forget to take TRACTINFECT

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

If you have missed a dose of TRACTINFECT, take the dose that you have missed as soon as you remember.

4. Possible side effects

TRACTINFECT can have side effects.

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

If any of the following happens, stop taking TRACTINFECT and 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 TRACTINFECT. 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:

- changes in the way your heart beats, for example, if you notice it beating faster (tachycardia),
- mild to severe abdominal cramps, bloody stools and /or fever may mean that you have an infection of the large intestine (pseudomembranous colitis),

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,
- sore throat (pharyngitis), runny or stuffy nose (rhinitis),
- loose stools (diarrhea), nausea, stomach pain (abdominal pain), heartburn, indigestion (dyspepsia),
- back pain,
- infection of the female genital organs with symptoms like inflammation, irritation, itching (vaginitis, vulvovaginitis),
- menstrual cramps (dysmenorrhoea),

- pain (non-localised), abnormal weakness or lack of energy (asthenia).

Less frequent side effects:

- burning or prickling sensation that is usually felt in the hands, arms, legs, or feet, but can also occur in other parts of the body (paraesthesia),
- vomiting;
- tiredness (fatigue).

Side effects with an unknown frequency

- Low blood pressure (hypotension),
- asthma, with symptoms such as wheezing, shortness of breath, coughing.

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/Publications/Index/8

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of TRACTINFECT.

5. How to store TRACTINFECT

Store all medicines out of reach of children.

Store at or below 25 °C.

Once the sachet is opened it should be used immediately.

Do not store in a bathroom.

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

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 TRACTINFECT contains

The active substance is fosfomycin trometamol equivalent to 3 g fosfomycin.

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

What TRACTINFECT looks like and contents of the pack

TRACTINFECT is a white to off-white powder with orange flavour packed in sachets. The sachets are made of paper, low density polyethylene and aluminium foil. Each sachet is packed in an outer cardboard carton.

Appearance of the product dissolved in water: clear to slightly opalescent, white solution, orange flavoured, free from undissolved particles.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Hotline: 0800 122 912

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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