PATIENT INFORMATION LEAFLET FOR ACTIZONE

SCHEDULING STATUS: **S4**

ACTIZONE™ 3 g Powder for Oral Solution

Fosfomycin Trometamol

Contains sugar: 2,244 g sucrose per sachet.

Read all of this leaflet carefully before you start taking ACTIZONE

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

2. What you need to know before you take ACTIZONE

3. How to take ACTIZONE

4. Possible side effects

5. How to store ACTIZONE

6. Contents of the pack and other information

1. What ACTIZONE is and what it is used for

ACTIZONE is an antibiotic.

ACTIZONE is used to treat urinary tract infection and cystitis (bladder infection) in women and men.

2. What you need to know before you take ACTIZONE

Do not take ACTIZONE

If you are hypersensitive (allergic) to fosfomycin trometamol or any of the other ingredients of ACTIZONE (listed in section 6).

Warnings and precautions

Take special care with ACTIZONE:

If you have any type of kidney disease.

If you have had severe diarrhoea (runny tummy) after taking other antibiotics. ACTIZONE may cause inflammation of the colon, with symptoms such as stomach cramps and fever.

ACTIZONE can cause diarrhoea, which may be a sign of a new infection. If you have diarrhoea that is watery or has blood in it, inform your doctor. Do not use any medicine to stop the diarrhoea unless your doctor has told you to.

Children

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

Other medicines and ACTIZONE

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

Do not take ACTIZONE with metoclopramide (a medicine used to relieve nausea and vomiting). Taking ACTIZONE and metoclopramide at the same time, has been shown to lower blood and urinary concentrations and should therefore be avoided.

ACTIZONE with food

Take ACTIZONE at least two hours before the next meal. Food delays and reduces absorption of fosfomycin trometamol, resulting in reduced blood and urinary concentrations.

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 healthcare provider for advice before taking ACTIZONE.

The safety and efficacy of ACTIZONE during pregnancy and breastfeeding has not been established.

Do not take ACTIZONE if you are breastfeeding as it can be distributed into breastmilk.

Driving and using machines

ACTIZONE may cause dizziness and fatigue. Do not drive or operate any machinery until you are sure that you can perform such activities safely.

ACTIZONE contains sucrose

Sucrose 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 ACTIZONE.

3. How to take ACTIZONE

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

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

The usual dose to treat bladder infections in women:

Ensure that you use 1 sachet only. This is a single dose treatment. Pour the contents of 1 sachet into a glass of water and stir. Drink the mixture immediately. To be taken at least two

hours before your next meal. Do not use more than a single dose (1 sachet). Using more than 1 sachet will not make ACTIZONE work any better and may increase side effects.

The usual dose to prevent infections in adult men undergoing surgical or diagnostic procedures:

This is a two-dose treatment. The first dose should be taken three hours before surgery. Pour the contents of 1 sachet into a glass of water and stir. Drink the mixture immediately. The second dose should be taken twenty-four hours after surgery. Do not use more 1 sachet (1 dose) at a time and do not take more than 2 doses. Using more than 1 sachet or taking more than 2 doses will not make ACTIZONE work any better and may increase side effects.

The proper use of ACTIZONE is very important. If you have any questions ask your doctor or pharmacist.

Keep to the dosage stated in this patient information leaflet or as your doctor has instructed you. You should always check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of ACTIZONE is too strong or too weak, tell your doctor or pharmacist.

If you take more ACTIZONE 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 forget to take ACTIZONE

For women with bladder infections:

You will only need to take 1 dose at least two hours before your next meal.

For adult men undergoing surgical or diagnostic procedures:

You will only need to take 2 doses. if you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

Then continue with your normal schedule.

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

4. Possible side effects

ACTIZONE can have side effects.

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

If any of the following happens, stop taking ACTIZONE 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; or
- fainting.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Diarrhoea;
- nausea (feeling sick);
- abdominal cramps or stomach pains;
- heartburn;
- headache;
- dizziness;
- sore throat;
- runny or stuffy nose;
- skin rash;
- itching;
- back pain;
- general body pain; or
- menstrual cramps.

Also tell your doctor immediately if you develop vaginal infection or inflammation.

Less frequent side effects:

- Tingling sensation (pins and needles);
- fast heartbeat;
- low blood pressure;
- pseudomembranous colitis (fever, watery diarrhea, stomach cramps, pain or tenderness, pus or mucus in your stool);
- angioedema (swelling of the lower layer of skin and tissue just under the skin or mucous membranes, often occurring on the face, tongue, abdomen, or arms and legs;
- tiredness.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of ACTIZONE.

5. How to store ACTIZONE

Store all medicines out of reach of children.

Store at or below 25 °C in a cool, dry place.

Store in the original packaging in order to protect from light and moisture.

Keep the foil sachet in the outer carton

Keep the container tightly closed

Do not use after the expiry date stated on the foil sachet and carton.

After mixing with water drink the mixture immediately.

Do not refrigerate or freeze.

Do not use ACTIZONE if you notice visible signs of deterioration.

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 ACTIZONE contains

The active substance is fosfomycin trometamol.

Each sachet contains 5,631 g fosfomycin trometamol equivalent to fosfomycin 3 g.

The other ingredient is sucrose.

What ACTIZONE looks like and contents of the pack

Powder for Oral Solution

White to almost white, granulated powder, without foreign particles.

1 Foil sachet contained in an outer cardboard carton.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

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