Summary of Product Characteristics of pharmaceutical product

1. Name of the medicinal product

Fosfopro (Fosfomycin Trometamol Powder 3gm)

2. Qualitative and quantitative composition

Each sachet contains:

Fosfomycin Trometamol BP

Eq. to

Fosfomycin……3mg

Excipient(s) with known effect:

Sucrose

For full list of excipients, see section 6.1.

3. Pharmaceutical form

Granules for oral solution.

A light orange-colored granules.

4. Clinical particulars

4.1 Therapeutic indications

Fosfomycin Trometamol is indicated for the treatment of acute, uncomplicated cystitis in women and female adolescents. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

Oral Use

Acute, uncomplicated cystitis in women and female adolescents (>12 years of age): 3 g Fosfomycin Trometamol once

Renal impairment:

Use of Fosfomycin Trometamol is not recommended in patients with renal impairment (creatinine clearance < 10 ml/min).

Paediatric population

The safety and efficacy of Fosfomycin Trometamol in children aged below 12 years of age have not been established.

Method of administration

For oral use.

For the indication of acute, uncomplicated cystitis in women and female adolescents it should be taken on an empty stomach (about 2-3 hours before or 2-3 hours after a meal), preferably before bedtime and after emptying the bladder.

The dose should be dissolved into a glass of water and taken immediately after its preparation.

Method of administration

Oral

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

Hypersensitivity reactions

Serious and occasionally fatal hypersensitivity reactions, including anaphylaxis and anaphylactic shock, may occur during Fosfomycin Trometamol treatment (see sections 4.3 and 4.8). If such reactions occur, treatment with Fosfomycin Trometamol must be discontinued immediately and adequate emergency measures must be initiated.

Clostridioides difficile-associated diarrhoea

Clostridioides difficile-associated colitis and pseudo-membranous colitis have been reported with Fosfomycin Trometamol and may range in severity from mild to lifethreatening (see section 4.8). Therefore, it is important to consider this diagnosis in patients who present with diarrhoea during or subsequent to the administration of fosfomycin. Discontinuation of therapy with Fosfomycin Trometamol and the administration of specific treatment for Clostridioides difficile should be considered. Medicinal products that inhibit peristalsis should not be given.

Paediatric population

The safety and efficacy of Fosfomycin Trometamol in children below 12 years of age have not been established. Therefore, this medicine should not be used in this age group (see section 4.2). Persistent infections and male patients

In case of persistent infections, a thorough examination and a re-evaluation of the diagnosis is recommended as this is often due to complicated urinary tract infections or the prevalence of resistant pathogens (e.g. Staphylococcus saprophyticus). In general, urinary tract infections in male patients have to be considered as complicated UTIs for which this medicinal product is not indicated.

Important information about excipients This medicine contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose - galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction Metoclopramide:

Concomitant administration of metoclopramide has been shown to lower serum and urinary concentrations of Fosfomycin Trometamol and should be avoided.

Other medicinal products that increase gastrointestinal motility may produce similar effects.

Food effects: Food may delay the absorption of fosfomycin trometamol, with consequent slight decrease in peak plasma levels and urinary concentrations. It is therefore preferable to take the medicinal product on an empty stomach or about 2 – 3 hours after meals.

Specific problems concerning the alteration in INR

Numerous cases of increased oral anticoagulant activity have been reported in patients receiving antibiotic therapy. Risk factors include severe infection or inflammation, age and poor general health. Under these circumstances, it is difficult to determinate whether the alteration in INR is due to the infectious disease or its treatment.

However, certain classes of antibiotics are more often involved and in particular: fluoroquinolones, macrolides, cyclins, cotrimoxazole and certain cephalosporins.

Paediatric population

Interaction studies have only been performed in adults.

4.6 Pregnancy, Fertility and Breast-feeding

Pregnancy

Only limited data on the safety of Fosfomycin Trometamol treatment during 1st trimester of pregnancy (n=152) are available. These data do not raise any safety signal for teratogenicity so far. Fosfomycin Trometamol crosses the placenta.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Fosfomycin Trometamol should only be used during pregnancy, if clearly necessary.

Breast-feeding

Fosfomycin Trometamol is excreted in human milk in low quantities. If clearly necessary, a single dose of oral Fosfomycin Trometamol can be used during breast-feeding.

Fertility

No data in humans are available.

In male and female rats oral administration of Fosfomycin Trometamol up to 1000 mg/kg/d did not impair fertility.

4.7 Effects on ability to drive and use machines

Effects on ability to drive and use machines.

No specific studies have been performed but patients should be informed that dizziness has been reported. This may influence some patients' ability to drive and use machines.

4.8 Undesirable effects

The most common adverse reactions following the single-dose administration of Fosfomycin Trometamol involve the gastrointestinal tract, mainly diarrhoea. These events are usually self-limited in duration and resolve spontaneously.

Tabulated list of adverse reactions

The following table displays ADRs that have been reported with the use of Fosfomycin Trometamol from either clinical-trial or post-marketing experiences.

The displayed frequency categories use the following convention:

Very common (≥ 1/10);

Common (≥ 1/100 to < 1/10);

Uncommon (≥ 1/1,000 to < 1/100);

Rare (≥ 1/10,000 to <1/1,000);

Very rare (<1/10,000),

Not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

System organ class	Adverse drug reactions		
	Common	Uncommon	Not known
Infections and infestations	Vulvovaginitis		
System organ	Adverse drug reactions		

class			
	Common	Uncommon	Not known
Immune system disorders			Anaphylactic reactions including anaphylactic shock, hypersensitivity
Nervous system disorders	Headache, dizziness		
Gastrointestinal disorders	Diarrhoea, nausea, dyspepsia, abdominal pain	Vomiting	Antibiotic-associated colitis
Skin and subcutaneous tissue disorders		Rash, urticaria, pruritus	Angioedema

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side affects you can help provide more information on the safety of this medicine.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

4.9 Overdose

Experience regarding the overdose of oral Fosfomycin Trometamol is limited. Cases of hypotonia, somnolence, electrolytes disturbances, thrombocytopenia and hypoprothrombinemia have been reported with parenteral use of fosfomycin.

In the event of overdose, the patient must be monitored (particularly for plasma/serum electrolyte levels), and treatment should be symptomatic and supportive. Rehydration is recommended to promote urinary elimination of the active substance.

Fosfomycin Trometamol is effectively cleared from the body by haemodialysis with a mean elimination half-life of approximately 4 hours.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibacterials for systemic use; Other antibacterials. ATC code: J01XX01

Mechanism of action

Fosfomycin Trometamol exerts a bactericidal effect on proliferating pathogens by preventing the enzymatic synthesis of the bacterial cell wall. Fosfomycin Trometamol inhibits the first stage of intracellular bacterial cell wall synthesis by blocking peptidoglycan synthesis.

Fosfomycin Trometamol is actively transported into the bacterial cell via two different transport systems (the sn-glycerol-3-phosphate and hexose-6 transport systems).

Pharmacokinetic/ pharmacodynamic relationship

Limited data indicate that Fosfomycin Trometamol most likely acts in a time-dependent manner.

Mechanism of resistance

Main mechanism of resistance is a chromosomal mutation causing an alteration of the bacterial Fosfomycin Trometamol transport systems. Further resistance mechanisms, which are plasmid-or transposon-borne, cause enzymatic inactivation of Fosfomycin Trometamol by binding the molecule to glutathione or by cleavage of the carbon-phosphorus-bond in the Fosfomycin Trometamol molecule, respectively.

Cross-resistance

Cross-resistance between Fosfomycin Trometamol and other antibiotic classes is not known.

Susceptibility testing breakpoints

The susceptibility breakpoints established by the European Committee on Antimicrobial Susceptibility Testing are as follows (EUCAST breakpoint table version 10):

Species	susceptible	resistant
Enterobacterales	≤ 32 mg/ml	> 32 mg/ml

The prevalence of acquired resistance of individual species may vary geographically and over time. Local information about the resistance situation is therefore necessary, particularly in order to ensure appropriate treatment of severe infections.

The following table is based on data from surveillance programs and studies. It comprises organisms relevant for the approved indications:

5.2 Pharmacokinetic properties

Absorption

After single-dose oral administration, Fosfomycin Trometamol has an absolute bioavailability of about 33-53%. Rate and extent of absorption are reduced by food, but the total amount of active substance excreted in the urine over time is the same. Mean urinary Fosfomycin Trometamol concentrations are maintained above an MIC threshold of 128 µg/mL for at least 24 h post 3 g oral dose in either the fasting or fed state, but the time to reach maximal concentrations in urine are delayed by 4 h. Fosfomycin Trometamol undergoes enterohepatic recirculation.

Distribution

Fosfomycin Trometamol does not appear to be metabolised. Fosfomycin Trometamol is distributed to tissues including the kidneys and bladder wall. Fosfomycin Trometamol is not bound to plasma proteins and crosses the placental barrier.

Elimination

Fosfomycin Trometamol is excreted unchanged mainly via the kidneys by glomerular filtration (40-50% of the dose is found in the urine) with an elimination halflife of about 4 hours after oral use and to a lesser extent

in faeces (18-28% of the dose). Even if food delays drug absorption, the total amount of drug excreted in the urine over time is the same.

Special populations

In patients with impaired renal function, the elimination half-life is increased proportionally to the degree of renal insufficiency. Urinary concentrations of Fosfomycin Trometamol in patients with impaired renal function remain effective for 48 hours after a usual dose if creatinine clearance is above 10 ml/min. In older people Fosfomycin Trometamol clearance is reduced in line with the age-related reduction in renal function.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity or toxicity to reproduction.

No carcinogenicity data are available for Fosfomycin Trometamol.

6. Pharmaceutical particulars

6.1 List of excipients

Sucrose

Neotame sweetener

Sodium methyl paraben

Sodium propyl paraben

Sunset yellow colour

Orange flavour

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

10gm granules in one sachet. Such 10-sachet packed in one carton.

6.6 Special precautions for disposal and other handling

Not applicable

7. Marketing Authorization Holder

PRO MED PHARMACEUTICALS LTD

P.O BOX 22953\00100, NAIROBI, KENYA

8. Marketing Authorization Number:

H2025/CTD12383/26923

9. Date of First (Registration) / Renewal of the (Registration)

21/10/2025

10. Date of Revision of the Text:

21/10/2025