PROPOSED CLEAN PROFESSIONAL INFORMATION

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

PROPAN MIST POT CIT SIMPLEX, 1,250 g, Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 ml contains:

Potassium citrate (monohydrate) 1,250 g

Preservatives:

Methylparaben 0,125 % m/v

Propylparaben 0,02 % m/v

Contains sugar: Each 15 ml contains 0,938 g sucrose.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution.

Slightly yellow, clear, mobile liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PROPAN MIST POT CIT SIMPLEX is used as a urinary alkaliser to alleviate symptoms associated with inflammatory conditions of the bladder.

PROPAN MIST POT CIT SIMPLEX may also be used during treatment with sulphonamides to prevent crystalluria.

4.2 Posology and method of administration

Posology

Adults: Two medicine measures (10 ml) well-diluted with water, three times per day with or immediately after meals.

Children: 6 to 12 years: One medicine measure (5 ml) well-diluted with water, three times per day with or immediately after meals.

Method of administration

To be taken orally.

4.3 Contraindications

PROPAN MIST POT CIT SIMPLEX should not be given with urinary antiseptics which require acid urine, such as methenamine mandelate and methenamine hippurate.

Hypersensitivity to potassium citrate or to any of the excipients of PROPAN MIST POT CIT SIMPLEX (see section 6.1).

PROPAN MIST POT CIT SIMPLEX should not be given to patients with renal failure or hyperkalaemia, irregular heartbeat and Addison's Disease**.**

4.4 Special warnings and precautions for use

- Use with care in patients suffering from renal insufficiency.
- Excessive administration may lead to metabolic alkalosis especially in patients with impaired renal function. Symptoms may include shortness of breath, muscle weakness and mental disturbances such as restlessness, convulsions and coma. Muscle hypertonicity, twitch and tetany may develop especially in hypocalcaemic patients.
- Alkalinizing agents do not eradicate bacteriuria, although they may temporarily relieve lower urinary tract symptoms.
- Concomitant use of PROPAN MIST POT CIT SIMPLEX with an antacid by patients with compromised renal function, may result in the absorption of dangerously high amounts of aluminium.
- Excessive intake of PROPAN MIST POT CIT SIMPLEX may result in hyperkaleamia, with resulting paraesthesia of the extremities, muscle weakness, paralysis, hypotension, cardiac dysrhythmia, heart block and cardiac arrest.
- Administer with care to patients receiving potassium sparing diuretics, in adrenal cortical insufficiency, acidosis and after tissue trauma.
- Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

PROPAN MIST POT CIT SIMPLEX should not be given with urinary antiseptics which require acid urine, such as methenamine mandelate and methenamine Hippurate (see section 4.3).

Concurrent administration of potassium-containing drugs, potassium sparing diuretics or other drugs that increase potassium levels (e.g. ACE inhibitors, ciclosporin, aliskiren) may lead to hyperkalaemia.

Citrates alkalinise the urine and thus may alter the urinary excretion of a number of medicines. This results in increased renal clearance of medicine such as salicylates, tetracyclines and barbiturates, and prolongation of the half-life of medicine such as sympathomimetics and stimulants.

Anti-bacterial activity of nitrofurantoin and methenamine may diminish.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy has not yet been established. In the absence of sufficient data, the use during pregnancy is not recommended.

Lactation

Safety in lactation has not yet been established. In the absence of sufficient data, the use during lactation is not recommended.

Fertility

No fertility data available.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use of machines have been performed.

4.8 Undesirable effects

b) Tabulated summary of adverse reactions

The undesirable effects listed are based on the MedDRAsystem organ classes (SOC) classification system. The frequency groupings listed conform to the following convention: Frequent, Less frequent and frequency unknown*

*Frequency unknown: the frequency of the side effect cannot be estimated from the available data.

System Organ class	Frequency	Adverse reaction
Gastrointestinal disorder	Frequency unknown	nausea, vomiting, diarrhoea and/or abdominal cramps.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety x SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

You may also report to Adcock Ingram Limited Pharmacovigilance department by email

Adcock.AEReports@adcock.com

4.9 Overdose

In overdosage, side effects can be precipitated and/or be of increased severity (**see section 4.8**).

Overdosage is accompanied by nausea, vomiting, abdominal pain symptoms due to hyperkalaemia and metabolic acidosis.

Fluid and electrolyte balance together with Electrocardiogram (ECG) should be closely monitored.

Moderate to severe hyperkalaemia is a medical emergency requiring prompt correction.

Treatment is symptomatic and supportive and consists mainly of correction of fluid and electrolyte balance.

Consult a doctor in known cases of overdosage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 18.3 Medicines acting on reno-urinary and genital system. Ion-exchange preparations.

Mechanism of action

Citrate and citric acid solutions are systematic and urinary alkalinisers thereby providing symptomatic relief of dysuria.

5.2 Pharmacokinetics properties

Potassium Citrate is absorbed and the citrate is metabolised to bicarbonate. Citric acid is metabolised to carbon dioxide and water. Oxidation is virtually complete with less than 5% of citrate being excreted unchanged in the urine.

5.3 Preclinical safety data

None known.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chloroform spirit

Chloroform

Methyl Paraben

Propyl Paraben

Purified water

Sucrose

Tincture aurant

6.2 Incompatibilities

Incompatible with calcium and strontium salts.

6.3 Shelf life

24 months.

6.4 Special precautions for storage ~~INSTRUCTIONS:~~

Store in a cool place (at or below 25 ºC).

Keep container tightly closed.

6.5 Nature of contents of container

Amber PVC bottles of 100 ml, 200 ml and an HDPE container of 2,5 L.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

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Erand Gardens

Midrand, 1685

Customer care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER (S)

H/18.3/1859

9. DATE OF FIRST AUTHORISZATION/RENEWAL OF THE AUTHORIZSATION

15 May 1997

10. DATE OF REVISION OF THE TEXT

23 May 2025