

PROPOSED CLEAN PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:** S0**PROPAN MIST POT CIT SIMPLEX, 1,250 g, Solution****Potassium citrate (monohydrate)****Contains sugar:****Each 15 ml contains 0,938 g sucrose.****Read all of this leaflet carefully before you start taking****PROPAN MIST POT CIT SIMPLEX**

- Keep this leaflet. You may need to read it again.
- Do not share PROPAN MIST POT CIT SIMPLEX with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not Improve.

What is in this leaflet

1. What PROPAN MIST POT CIT SIMPLEX is and what it is used for
2. What you need to know before you take PROPAN MIST POT CIT SIMPLEX
3. How to take PROPAN MIST POT CIT SIMPLEX

4. Possible side effects
5. How to store PROPAN MIST POT CIT SIMPLEX
6. Contents of the pack and other information

1. What PROPAN MIST POT CIT SIMPLEX is and what it is used for

PROPAN MIST POT CIT SIMPLEX is a urinary alkaliser used 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.

2. What you need to know before you take PROPAN MIST POT CIT SIMPLEX

Do not take PROPAN MIST POT CIT SIMPLEX:

- If you are hypersensitive to Potassium citrate (monohydrate) or to any of the other ingredients of PROPAN MIST POT CIT SIMPLEX (listed in section 6).
- If you are taking urinary antiseptics which require urine acid, such as methenamine mandelate and methanamine hippurate.
- If you have kidney failure.
- If you have irregular heartbeat.
- If you have high levels of potassium in your blood.
- If you are suffering from Addison's Disease, a disease in which adrenal glands do not produce enough hormones.

Warnings and precautions

Take special care with PROPAN MIST POT CIT SIMPLEX:

- If you are suffering from kidney problems as excessive administration may lead to a state of increased pH (basicity of the body fluids) beyond normal range. Symptoms may include shortness of breath, muscle weakness and mental disturbances such as restlessness, rapid involuntary muscle contractions and coma. Twitch and tetany may develop especially if you have too little calcium in your blood.
- As excessive intake may lead to high levels of potassium in your blood, which can ultimately result into pins and needle sensation in the hands and feet muscle weakness or altered muscle function, low blood pressure and cardiovascular problems including irregular heartbeat and heart block.
- If you are receiving medicine which increase urination such as ACE inhibitors, ciclosporin, aliskiren (without the loss of potassium).
- If you suffer from Adrenal Cortical Insufficiency (malfunctioning of adrenal gland whereby less hormones are produced)
- If you experience excessive build-up of acid in the body.
- If you have muscle injury.
- Alkalinizing agents do not eliminate bacteria in the urine, although they may temporarily relieve lower urinary tract symptoms.

Other medicine and PROPAN MIST POT CIT SIMPLEX

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

- PROPAN MIST POT CIT SIMPLEX should not be given together with urinary antiseptics (medicine which prevent bacterial infection in urinary tract) such as methenamine mandelate and methenamine hippurate.
- Concurrent use of PROPAN MIST POT CIT SIMPLEX with antacid by patients with compromised renal function, may result in the absorption of dangerously high amounts

of aluminium. Antacid is a medicine which reduces the amount of acid in the stomach,

- Citrates alkalise the urine and thus may alter the urinary excretion of a number of medicines. This may result in increased or decreased renal clearance of some medicine.
- The anti-bacterial efficacy of nitrofurantoin and methenamine (antibiotic medicines) may diminish.

Pregnancy, and breastfeeding and Fertility

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 health care provider for advice before taking PROPAN MIST POT CIT SIMPLEX.

No fertility data available.

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

Driving and using machines

It is not always possible to predict to what extent PROPAN MIST POT CIT SIMPLEX may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PROPAN MIST POT CIT SIMPLEX affects them.

PROPAN MIST POT CIT SIMPLEX contains sucrose

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

3. How to take PROPAN MIST POT CIT SIMPLEX

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

Always take PROPAN MIST POT CIT SIMPLEX exactly as described in this leaflet or as your pharmacist has told you.

Check with your pharmacist if you are not sure.

The usual dose is:

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.

DO NOT EXCEED THE STATED DOSE.

If you take more PROPAN MIST POT CIT SIMPLEX than you should

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

Overdose may be accompanied by nausea, vomiting, abdominal pain symptoms, due to high levels of potassium in the blood and the accumulation of acid in the body. Close monitoring is required for fluid and electrolyte balance and in cases where an electrocardiogram is being conducted.

If you forget to take PROPAN MIST POT CIT SIMPLEX

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

4. Possible side effects

Not all side effects reported for PROPAN MIST POT CIT SIMPLEX are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking PROPAN MIST POT CIT SIMPLEX, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

Frequency not known

- Nausea
- Vomiting
- Diarrhoea
- Abdominal cramps

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 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 SAHPRA website.

By reporting side effects, you can help provide more information on the safety of PROPAN MIST POT CIT SIMPLEX.

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

Adcock.AEReports@adcock.com

5. How to store PROPAN MIST POT CIT SIMPLEX

- Store at or below 25 °C
- Protect from light
- Do not refrigerate
- Store in the original package
- Keep the container tightly closed
- Do not use after expiry date stated on the label
- Do not dispose of unused medicine in drains or sewerage
systems (e.g toilets)

6. Contents of the pack and other information

What PROPAN MIST POT CIT SIMPLEX contains:

The active substance is Potassium citrate (monohydrate) 1,250 g.

The other ingredients are chloroform spirit, chloroform, methyl paraben, propyl paraben, purified water, sucrose and tincture aurant.

What PROPAN MIST POT CIT SIMPLEX looks like and contents of the pack

PROPAN MIST POT CIT SIMPLEX is a slightly yellow, clear, mobile liquid.

It is packed in amber PVC bottles of 100 ml, 200 ml and an HDPE container of 2,5 L.

Holder of Certificate of registration

Adcock Ingram Limited

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