**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** **S0**

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

**Potassium citrate**

**Contains sugar:**

**0,938 g sucrose.**

**Read all of this leaflet carefully because it contains important information for you.**

PROPAN MIST POT CIT SIMPLEX is available without a doctor's prescription for you to treat a mild illness.

Nevertheless, you still need to use PROPAN MIST POT CIT SIMPLEX carefully to get best results from it.

- 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 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 an acidic urine environment to be effective, such as methenamine mandelate and methenamine hippurate.
- If you have kidney failure.
- If you have an 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 medicines which increase urination such as ACE inhibitors, ciclosporin, and aliskiren.
- If you suffer from adrenal cortical insufficiency (malfunctioning of adrenal gland whereby less hormones are produced)
- If you have muscle injury.
- If you experience excessive build-up of acid in the body.
- If you have compromised renal function and you are taking antacids, which are medicines that reduce the amount of acid in the stomach. The concurrent use of these medicines may result in absorption of dangerously high amounts of aluminium.
- Alkalinizing agents do not eliminate bacteria in the urine, although they may temporarily relieve lower urinary tract symptoms.

**Other medicines and PROPAN MIST POT CIT SIMPLEX**

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

- PROPAN MIST POT CIT SIMPLEX should not be given together with urinary antiseptics (medicines which prevent bacterial infection in urinary tract) such as methenamine mandelate and methenamine hippurate.
- Citrates alkalinise 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, 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, doctor or pharmacist or nurse 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.

Shake the bottle before use.

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

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

Overdosage 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 the Adcock Ingram Limited Pharmacovigilance department by email

Adcock.AEReports@adcock.com

## 5. How to store PROPAN MIST POT CIT SIMPLEX

- Store all medicines out of reach of children
- Store in a cool place (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
- Return all unused medicines to your pharmacist.

## 6. Contents of the pack and other information

**What PROPAN MIST POT CIT SIMPLEX contains:**

The active substance is potassium citrate 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 amber HDPE container of 2,5 L.

Not all pack sizes may be marketed.

**Holder of Certificate of registration**

Adcock Ingram Limited

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Erand Gardens

Midrand, 1685

Customer care: 0860 ADCOCK / 232625

**This leaflet was last revised in**

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**Registration number**

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**PASIËNT INLIGTINGSBILJET**

**SKEDULERINGSTATUS: S0**

**PROPAN MIST POT CIT SIMPLEX, 1 250 g, Oplossing**

**Kaliumsitraat**

**Bevat suiker:**

**0,938 g sukrose.**

**Lees hierdie hele biljet sorgvuldig deur, want dit bevat belangrike inligting vir u.**

PROPAN MIST POT CIT SIMPLEX is beskikbaar sonder 'n doktersvoorskrif om 'n minder ernstige siekte te behandel.

Nietemin moet u steeds PROPAN MIST POT CIT SIMPLEX versigtig gebruik om die beste resultate daaruit te verkry.

- Hou hierdie biljet. U mag dit dalk weer moet lees.
- Moenie PROPAN MIST POT CIT SIMPLEX met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.
- U moet 'n dokter spreek indien u simptome vererger of nie verbeter nie.

**Wat is in hierdie biljet**


1. Wat PROPAN MIST POT CIT SIMPLEX is en waarvoor dit gebruik word
2. Wat u moet weet voordat u PROPAN MIST POT CIT SIMPLEX neem.
3. Hoe om PROPAN MIST POT CIT SIMPLEX te neem
4. Moontlike newe-effekte
5. Hoe om PROPAN MIST POT CIT SIMPLEX te bêre
6. Inhoud van die verpakking en ander inligting


## 1. Wat PROPAN MIST POT CIT SIMPLEX is en waarvoor dit gebruik word

PROPAN MIST POT CIT SIMPLEX is 'n urien-alkaliniseerder wat gebruik word om simptome geassosieer met inflammatoriese toestande van die blaas, te verlig. PROPAN MIST POT CIT SIMPLEX kan ook tydens behandeling met sulfonamiede gebruik word om kristalurie te voorkom.

## 2. Wat u moet weet voordat u PROPAN MIST POT CIT SIMPLEX neem.

Moet nie PROPAN MIST POT CIT SIMPLEX neem nie:

- Indien u hipersensitief is vir kaliumsitraat of enige van die ander bestanddele van PROPAN MIST POT CIT SIMPLEX (gelys in afdeling 6).
- Indien u urien-antiseptika neem wat 'n suur urien-omgewing benodig om effektief te wees, soos metenamienmandelaat en metenamienhippuraat.
- Indien u nierversaking het.
- Indien u 'n onreëlmatige hartklop het.
- Indien u hoë vlakke van kalium in u bloed het.
- Indien u aan Addison se siekte ly, 'n siekte waar bynierkliere nie genoeg hormone produseer nie.

**Waarskuwings en voorsorgmaatreëls**

Wees versigtig met PROPAN MIST POT CIT SIMPLEX:

- Indien u aan nierprobleme ly, kan oormatige toediening lei tot 'n toestand van verhoogde pH (basisgehalte van die liggaamsvloeistowwe) buite die normale grens. Simptome kan kortasem, spierswakheid en geestelike versteurings soos rusteloosheid, vinnige onwillekeurige spierkontraksies en koma insluit. Spiere wat spring en tetanie kan ontwikkel, veral indien u te min kalsium in u bloed het.
- Aangesien oormatige inname kan lei tot hoë vlakke van kalium in u bloed, wat uiteindelik kan lei tot naalde-en-spelde sensasie in hande en voete, spierswakheid of veranderde spierfunksie, lae bloeddruk en kardiovaskulêre probleme, insluitend onreëlmatige hartklop en hartblok.
- Indien u medisyne ontvang wat urinering verhoog, soos AOE-inhibeerders, siklosporien en aliskiren.
- Indien u ly aan bynier-kortikale ontoereikendheid (wanfunksionering van die bynier waardeur minder hormone geproduseer word)
- Indien u 'n spierbesering het.
- Indien u oormatige opbou van suur in die liggaam ervaar.
- Indien u ingeperkte nierfunksie het en u teensuurmiddels neem, wat medisyne is wat die hoeveelheid suur in die maag verminder. Die gelyktydige gebruik van hierdie medisyne kan lei tot die absorpsie van gevaarlike hoë hoeveelhede aluminium.
- Alkaliniserende middels verwyder nie bakterieë in die urien nie, alhoewel hulle tydelik die simptome van die onderste urienweg kan verlig.

**Ander medisyne en PROPAN MIST POT CIT SIMPLEX**

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medikasie neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

- PROPAN MIST POT CIT SIMPLEX moet nie saam met urien-antiseptika (medisyne wat bakteriële infeksies in die urienweg voorkom) soos metenamienmandelaat en metenamienhippuraat gegee word nie.
- Sitrate alkaliseer die urien en kan dus die urienuitskeiding van 'n aantal medisyne verander. Dit kan lei tot verhoogde of verminderde nieruitskeiding van sekere medisyne.
- Die antibakteriese doeltreffendheid van nitrofurantoïen en metenamien (antibiotika) kan afneem.

**Swangerskap, borsvoeding en vrugbaarheid**

Indien u swanger is of borsvoed, dink u mag swanger wees of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u PROPAN MIST POT CIT SIMPLEX neem**.**

Geen vrugbaarheidsdata beskikbaar nie.

Veiligheid tydens swangerskap en borsvoeding is nog nie vasgestel nie. In die afwesigheid van voldoende data word die gebruik tydens swangerskap en laktasie nie aanbeveel nie.

**Bestuur en gebruik van masjinerie**

Dit is nie altyd moontlik om te voorspel in watter mate PROPAN MIST POT CIT SIMPLEX met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet seker maak dat hulle nie aan bogenoemde aktiwiteite deelneem nie totdat hulle bewus is van die mate waartoe PROPAN MIST POT CIT SIMPLEX hulle beïnvloed.

**PROPAN MIST POT CIT SIMPLEX bevat sukrose**

Indien u dokter u ingelig het dat u 'n onverdraagsaamheid teenoor sekere suikers het, kontak u dokter voordat u hierdie medisinale produk neem.

## 3. Hoe om PROPAN MIST POT CIT SIMPLEX te neem

Moet nie medikasie wat aan u voorgeskryf is, met enige ander persoon deel nie.

Neem altyd PROPAN MIST POT CIT SIMPLEX presies soos beskryf in hierdie biljet of soos u dokter, apteker of verpleegkundige u ingelig het.

Vra u apteker indien u nie seker is nie.

**Die algemene dosis is:**

*Volwassenes:* Twee medisynemates (10 ml) goed verdun met water, drie keer per dag met of onmiddellik na etes.

*Kinders:* 6 tot 12 jaar: Een medisynemate (5 ml) goed verdun met water, drie keer per dag met of onmiddellik na etes.

Skud die bottel voor gebruik.

**Indien u meer PROPAN MIST POT CIT SIMPLEX neem as wat u moes**

In die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een van die twee beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Oordosering kan gepaard gaan met naarheid, braking, buikpyn simptome, as gevolg van hoë vlakke van kalium in die bloed en die ophoping van suur in die liggaam. Noukeurige monitering is nodig vir vloeistof- en elektrolietbalans en in gevalle waar 'n elektrokardiogram uitgevoer word.

**Indien u vergeet om PROPAN MIST POT CIT SIMPLEX te neem**

Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

## 4. Moontlike newe-effekte

Nie alle newe-effekte wat vir PROPAN MIST POT CIT SIMPLEX aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige negatiewe effekte ervaar terwyl u PROPAN MIST POT CIT SIMPLEX gebruik, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Lig u dokter in indien u enige van die volgende opmerk:

*Frekwensie nie bekend nie*

- Naarheid
- Braking
- Diarree
- Abdominale krampe

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, lig asseblief u dokter of apteker in.

**Aanmelding van newe-effekte**

Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (who-umc.org) wat gevind kan word op die SAHPRA se webwerf.

Deur newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van PROPAN MIST POT CIT SIMPLEX.

U kan dit ook per e-pos by die Adcock Ingram Limited Pharmacovigilance-afdeling aanmeld

Adcock.AEReports@adcock.com

## 5. Hoe om PROPAN MIST POT CIT SIMPLEX te bêre

- Bêre alle medisyne buite bereik van kinders
- Bêre dit op 'n koel plek (teen of benede 25 °C)
- Beskerm teen lig
- Moenie in die yskas verkoel nie
- Bêre in die oorspronklike verpakking
- Hou die houer dig toe
- Moenie gebruik ná die vervaldatum wat op die etiket aangedui is nie
- Neem alle ongebruikte medisyne terug na u apteker.

## 6. Inhoud van die verpakking en ander inligting

**Wat PROPAN MIST POT CIT SIMPLEX bevat:**

Die aktiewe bestanddeel is kaliumsitraat 1 250 g.

Die ander bestanddele is chloroform spiritus, chloroform, metielparabeen, propielparabeen, gesuiwerde water, sukrose en bitterlemoenskil-tinktuur.

**Hoe PROPAN MIST POT CIT SIMPLEX lyk en inhoud van die verpakking**

PROPAN MIST POT CIT SIMPLEX is 'n effens geel, deurskynende, mobiele vloeistof.

Dit word verpak in amber PVC-bottels van 100 ml, 200 ml en amber HDPE-houer van 2,5 L.

Nie alle verpakkingsgroottes word bemark nie.

**Houer van die Sertifikaat van Registrasie**

Adcock Ingram Limited

New Road 1,

Erand Gardens

Midrand, 1685

Kliëntediens: 0860 ADCOCK / 232625

**Hierdie biljet is laas hersien op**

23 Mei 2025

**Registrasienommer**

H/18.3/1859

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| Namibië: NS0 18.05.3/0254 |

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| Botswana: B9322525 |