1.5.5.2 Patient Information Leaflet -CLEAN

1.3.2 Clean Proposed Patient Information Leaflet

SCHEDULING STATUS

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URI-ALK (effervescent tablets)

Sodium Citrate.2H_2O	**615 mg**
Sodium Bicarbonate	**1362 mg**
Tartaric Acid	**860 mg**
Citric Acid Anhydrous	**700 mg**

Contains sweetener: Aspartame 28,500 mg per tablet

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

- URI-ALK is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use URI-ALK carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share URI-ALK with any other person.
- Ask your healthcare 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 URI-ALK is and what it is used for.

2. What you need to know before you take URI-ALK.

3. How to take URI-ALK.

4. Possible side effects.

5. How to store URI-ALK.

6. Contents of the pack and other information.

1. What URI-ALK is and what it is used for

URI-ALK belongs to a group of medicines acting on the genito-urinary system.

URI-ALK is used to relieve gastric acidity as well as for its urinary alkalinising properties.

2. What you need to know before you take URI-ALK

Do not take/give URI-ALK:

- if you are hypersensitive (allergic) to sodium citrate, sodium bicarbonate, citric acid anhydrous and tartaric acid or any of the other ingredients of URI-ALK (listed in section 6);
- if you have severe kidney problems. Please discuss this with your doctor;
- if you have metabolic disturbances with alkalosis (rise in the level of alkali in the blood resulting in feeling of weakness or cramping, hypocalcaemia (deficiency of calcium in the bloodstream) or hypochlorhydria (an abnormally low level of hydrochloric acid in the stomach);
- to children under 6 years of age;
- if you are currently taking any of the following medicines:
- Urinary tract antiseptics which require acid urine, such as methanamine mandelate and methanamine hippurate.

Warnings and precautions

Take special care with URI-ALK if you:

- have kidney insufficiency/problems,
- are the caregiver, you must not give URI-ALK to children under 6 years of age.

Tell your doctor or healthcare provider before taking URI-ALK if you:

- are currently taking other medicines, as URI-ALK may interact with these medicines and cause unwanted or adverse effects;
- suffer from kidney insufficiency/problems. You may have to go for blood tests to determine if your kidneys are functioning properly;
- are taking other antacids and you have compromised kidney function, as this may result in the absorption of dangerously high amounts of aluminium;
- are suffering from congestive heart failure and high blood pressure;
- are suffering from an ulcer of the stomach or gut;
- are on a sodium-restricted diet, as you should not take URI-ALK;
- have cirrhosis (a chronic disease of the liver caused by alcoholism or inflammation of the liver);
- have swelling of the feet, hands or ankles (peripheral oedema);
- have been diagnosed with pulmonary oedema (fluid accumulating in the lungs);
- are pregnant and suffering from eclampsia (seizures in pregnant women with high blood pressure).

Please note that this alkalinising agent does not eradicate bacteriuria (the presence of bacteria in the urine) although it may temporarily relieve lower urinary tract symptoms.

Children and adolescents

The caregiver must not give URI-ALK to children under 6 years of age.

Other medicines and URI-ALK

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

Tell your doctor if you are taking any of the following medicines:

- *Urinary tract antiseptics,* such as methenamine mandelate and methenamine hippurate (an antibiotic that eliminates bacteria that causes urinary tract infections) (see "Do not take URI-ALK ").
- *Antacids:*

  Any other antacid, including aluminium-containing antacids, since it may cause abnormally high alkalinity of the blood and body fluids, may promote the development of kidney stones and may cause elevated sodium levels in the blood. It may cause absorption of dangerously high amounts of aluminium.
- *Quinolone antibiotics*, e.g. ciprofloxacin, norfloxacin or ofloxacin.
- *Salicylates,* e.g. aspirin used for pain, inflammation and fever and methyl salicylate/wintergreen oil, for treatment of skin conditions and joint pain.
- *Tetracyclines, doxycycline used as antibiotics.*

  You should not take URI-ALK within 1 to 2 hours of these antibiotics.
- *Ketoconazole*:

  You should take URI-ALK at least 2 hours after ketoconazole (medication used to treat infections caused by fungus or yeast).

URI-ALK with food and drink and alcohol

URI-ALK must be taken on an empty stomach and followed with additional water.

Pregnancy and breastfeeding and fertility

The safety of URI-ALK during pregnancy and whilst breastfeeding has not been established.

If you are pregnant or breastfeeding your baby, 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 URI-ALK.

Driving and using machinery

It is not always possible to predict to what extent URI-ALK 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 URI-ALK affects them.

URI-ALK contains aspartame

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take URI-ALK

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

Always take URI-ALK exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose is:

Adults:

- One to two effervescent tablets in half a glass of cold water 2 - 3 times daily, taken on an empty stomach and followed with additional water.
- Drink after the tablet has completely effervesced.

Children (6 - 12 year):

- One effervescent tablet in half a glass of cold water 2 to 3 times daily, taken on an empty stomach and followed with additional water.
- Drink after the tablet has completely effervesced.

If you have the impression that the effect of URI-ALK is too strong or too weak, tell your doctor or pharmacist.

If you take more URI-ALK than you should

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

If you forget to take a dose of URI-ALK

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

4. Possible side effects

URI-ALK can have side effects.

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

If any of the following happens, stop taking URI-ALK and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- shortness of breath, muscle weakness, mental disturbances such as restlessness convulsions and coma, especially if you suffer from impaired kidney function. These are symptoms of metabolic alkalosis,
- seizures, swelling of feet or lower legs, weakness, oedema and possible effect on the cerebral, pulmonary or peripheral circulations (excessive doses may lead to sodium overloading and hyperosmolality).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported less frequently:

- increased thirst,
- dizziness,
- fast heartbeat,
- high blood pressure,
- irritability,
- muscle twitching,
- restlessness,
- stomach cramps, diarrhoea or loose bowel movement.

The following side effects have been reported but the frequency is unknown:

- muscle hypertonicity (spasms), twitching and tetany, especially if you have low blood calcium levels,
- abdominal distention, flatulence, belching and nausea may occur if URI-ALK effervescent granules are taken before effervescence is complete (see "How to take URI-ALK").

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of URI-ALK.

5. How to store URI-ALK

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Store in a cool, dry place.

Do not store in a bathroom.

Do not use after the expiry date stated on the label/carton/bottle.

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 URI-ALK contains:

The active substances are:

Sodium Citrate.$2H_2O$

Sodium Bicarbonate

Tartaric Acid

Citric Acid Anhydrous

The other ingredients are*:*

Aspartame, lemon flavour, polyethylene glycol, quinolene yellow colourant, sodium carbonate anhydrous.

What URI-ALK looks like and contents of the pack:

What URI-ALK looks like:

A round, light yellow effervescent tablet with flat sides, and rough surfaces.

After effervescence, a light yellow, lemon-flavoured, clear solution results.

Contents of the pack:

URI-ALK is packed in seamless aluminium tubes, with white lacquered (painted) inner and outer surfaces and closed with a white, low-density poly-ethylene press-on cap with a spiral stabiliser, with a drier cavity filled with a self-indicating silica gel drier and a flat carton retainer. Each aluminium tube contains 12 tablets.

or

URI-ALK is packed in white, polypropylene, plastic tubes and closed with a white, low-density, poly-ethylene, press-on cap with a spiral stabiliser, with a drier cavity filled with self-indicating silica gel drier and a flat carton retainer. Each plastic tube contains 12 tablets.

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Holder of Certificate of Registration and Manufacturer

MEDCHEM PHARMACEUTICALS (PTY) LTD.

5 GOEDE HOOP

18 HILLVIEW

NEWLANDS

PRETORIA

SOUTH AFRICA

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.