PROFESSIONAL INFORMATION

ALKAFIZZ LEMON

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

ALKAFIZZ LEMON

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each (4 g) contains:

Sodium citrate	0,613 g
Sodium bicarbonate	1,716 g
Citric acid anhydrous	0,702 g
Tartaric acid	0,858 g
Contains sugar (liquid glucose)	0,34 mL

For the full list of excipients, see **section 6.1**.

3. PHARMACEUTICAL FORM

Effervescent granules.

White to straw coloured granules with a lemon odour and a sweet/sour slightly lemon taste.

After reconstitution with water a clear to straw coloured solution with a slight lemon odour is obtained.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ALKAFIZZ LEMON is indicated as a gastric antacid and urinary alkalinising agent. As a urinary alkaliniser, ALKAFIZZ LEMON can be used to alleviate symptoms associated with inflammatory conditions of the bladder. ALKAFIZZ LEMON can be used to prevent crystalluria during sulphonamide treatment.

4.2 Posology and method of administration

Posology

Adults

One to two 5 mL medicine measures (4 g to 8 g) in half a glass of water, 3 to 4 times daily, taken on an empty stomach and followed with additional water. Drink after effervescence (see **section 4.8).**

Long-term therapy: One 5 mL (4 g) medicine measure daily.

Paediatric population

Children (6 - 12 years)

One 5 mL medicine measure (4 g) in half a glass of water, 2 or 3 times daily, taken on an empty stomach and followed with additional water. Drink after effervescence (see **section 4.8)**.

Method of administration

Take on an empty stomach, followed with additional water. Drink after effervescence.

4.3 Contraindications

ALKAFIZZ LEMON is contraindicated in:

- Patients with known hypersensitivity to sodium bicarbonate, citric acid, sodium citrate, tartaric acid or to any of the excipients used in the formulation of ALKAFIZZ LEMON (see **section 6.1**)
- Patients with severe renal disease and metabolic disturbances with alkalosis, hypocalcaemia or hypochlorhydria.
- ALKAFIZZ LEMON should not be given with urinary tract antiseptics which require an acid urine, such as methanamine mandelate and methanamine hippurate.(see **section 4.5).**

4.4 Special warnings and precautions for use

ALKAFIZZ LEMON should be used with care in patients suffering from renal insufficiency.

Alkalinising agents do not eradicate bacteriuria although they may temporarily relieve lower urinary tract symptoms.

Concomitant use of ALKAFIZZ LEMON with an antacid by patients with compromised renal function may result in the absorption of dangerously high amounts of aluminium (see **section 4.5).**

Patients suffering from congestive cardiac failure and hypertension should not use ALKAFIZZ LEMON except under the advice and supervision of a doctor.

Caution should be used in patients with peptic ulceration and patients with renal abnormalities, to avoid the condition of metabolic alkalosis. Patients with renal disease should have periodic determinations of serum electrolytes to ensure that acid-base balance is maintained.

Should not be taken by patients on a sodium-restricted diet.

Caution should also be observed in patients with cirrhosis of the liver, congestive heart failure or hypertension, peripheral and pulmonary oedema and pre-eclampsia.

Liquid Glucose

ALKAFIZZ LEMON contains **liquid glucose.**

Patients with rare glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Antacids:

Concurrent use of antacids with citrates may result in systemic alkalosis.

Concomitant administration of antacids with sodium citrate and sodium bicarbonate may promote the development of calcium stones in patients with uric acid stones and may also cause hypernatraemia.

Concurrent use of aluminium-containing antacids with citrate salts can increase aluminium absorption, possibly resulting in acute aluminium toxicity, especially in patients with renal insufficiency (see **section 4.4**).

Quinolones:

Citrates may reduce the solubility of ciprofloxacin, norfloxacin, or ofloxacin in the urine. Patients should be observed for signs of crystalluria and nephrotoxicity.

Salicylates:

Concurrent use of salicylates with citrates may increase the urinary excretion and decrease the therapeutic effects of salicylates due to alkalinization of the urine.

Tetracyclines:

Tetracycline absorption may be decreased when it is used concurrently with sodium bicarbonate because of the increase in intragastric pH. ALKAFIZZ LEMON should not be taken within 1 to 2 hours of tetracyclines.

Ketoconazole:

Sodium bicarbonate may cause increased gastrointestinal pH; concurrent administration with sodium bicarbonate may result in a marked reduction in absorption of ketoconazole; patients should take ALKAFIZZ LEMON at least 2 hours after ketoconazole.

Methenamine:

Alkalinisation of the urine caused by sodium bicarbonate and citrates may reduce the effectiveness of methenamine by inhibiting its conversion to formaldehyde; concurrent use with ALKAFZZ LEMON is not recommended.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety of citrates, and therefore ALKAFIZZ LEMON in pregnancy has not been established.

Breastfeeding:

Caution should be exercised when administered to a breastfeeding mother.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Metabolism and nutrition disorders

Less frequent:	Increased thirst. Hypernatraemia (fast heartbeat, dizziness, high blood pressure, muscle twitching, irritability, seizures, restlessness, swelling of feet or lower legs, weakness) may occur.
Frequency unknown:	Metabolic alkalosis (muscle weakness, shortness of breath and mental disturbances such as restlessness, convulsions and coma) may occur especially in patients with renal

dysfunction. Excessive doses may lead to sodium overloading and hyperosmolality with resulting oedema and possible effect on the cerebral, pulmonary or peripheral circulations

Gastrointestinal disorders:

Less frequent:	Stomach cramps and laxative effect (loose bowel movements or diarrhoea) may occur.
Frequency unknown:	Abdominal distension, belching, flatulence and nausea may occur if ALKAFIZZ LEMON is taken before effervescence is complete.

Musculoskeletal, connective tissue and bone disorders:

Frequency unknown:	Muscle hypertonicity, twitching and tetany may develop, especially in hypocalcaemic patients.

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 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 and to Cipla Medpro (Pty) Ltd at drugsafetysa@cipla.com or telephone 080 222 6662 (toll free).

4.9 Overdose

Overdosage may result in metabolic alkalosis and hypernatraemia (see **section 4.8**).

Treatment is symptomatic and supportive and consists mainly of correction of fluid and electrolyte balance with complete withdrawal of the preparation. A doctor should be consulted in known cases of overdosage.

In these cases, regular electrolyte estimations should be taken and the necessary therapy instituted.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 18.3 Medicines acting on genito-urinary system - Ion exchange preparations.

ALKAFIZZ LEMON has gastric antacid as well as urinary alkalinising properties.

Urinary alkaliniser

Sodium bicarbonate increases the excretion of free bicarbonate ions in the urine, thus raising the urinary pH. By maintaining alkaline urine, the actual dissolution of uric acid stones may be accomplished.

Citrates (sodium citrate and citric acid) are metabolised to bicarbonates (see above).

Gastric antacid

Sodium bicarbonate, sodium citrate and citric acid react chemically to neutralize or buffer existing quantities of gastric hydrochloric acid but have no direct effect on its output. This action results in an increased pH value of stomach contents, thus providing relief of hyperacidity symptoms.

5.2 Pharmacokinetic properties

Sodium bicarbonate

Renal elimination; CO_2 (carbon dioxide) formed is eliminated via the lungs.

Sodium citrate and citric acid:

Citrates are oxidized in the body to form sodium bicarbonate. This is eliminated via the urine and less than 5 % is excreted unchanged.

Tartaric acid:

Tartaric acid is absorbed from the gastrointestinal tract but up to 80 % of an ingested dose is probably destroyed by micro-organisms in the lumen of the intestine before absorption occurs. Absorbed tartaric acid is excreted unchanged in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Lemon flavour, Permaseal 60301-71
- Liquid glucose

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store in a dry place, at or below 25 °C.

Close the container tightly after opening.

Do not refrigerate or freeze.

Keep the bottle in the outer carton.

6.5 Nature and contents of container

ALKAFIZZ LEMON is available in clear glass bottles with screw cap and dosage measure, or plastic bottles with a screw cap, each bottle containing 60 g, 100 g or 120 g of effervescent granules.

ALKAFIZZ LEMON is available in 4 g sachets with 30 sachets in an outer carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

After reconstitution with water a clear to straw coloured solution with a slight lemon odour is obtained.

7. HOLDER OF CERTIFICATE OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc Du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

8. REGISTRATION NUMBER(S)

29/18.3/03789**.**

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19 April 1995

10. DATE OF REVISION OF THE TEXT

24 January 2025

Namibia: NS0 12/18.3/0114