SCHEDULING STATUS: S0

PROPRIETARY NAME (and dosage form):

ALKAFIZZ (Effervescent granules)

COMPOSITION:
Each medicine measure (4 g) contains:

Sodium citrate	0.613 g
Sodium bicarbonate	1.716 g
Citric acid anhydrous	0.702 g
Tartaric acid	0.858 g
Sugar (liquid glucose)	0.34 ml

PHARMACOLOGICAL CLASSIFICATION:
A 18.3 Medicines acting on genito-urinary system (ion exchange preparations).

PHARMACOLOGICAL ACTION:
ALKAFIZZ effervescent granules have gastric antacid as well as urinary alkalinising properties.

INDICATIONS:
ALKAFIZZ is a gastric antacid and urinary alkalinising agent.

CONTRA-INDICATIONS:
ALKAFIZZ effervescent granules should not be administered to patients:
- With known hypersensitivity to any of the ingredients.
- With severe renal disease and metabolic disturbances with alkalosis, hypocalcaemia or hypochlorhydria.
- Who use urinary tract antiseptics which require acidic urine, such as methenamine mandelate and methenamine hippurate (see **"INTERACTIONS"**).

WARNINGS:
ALKAFIZZ effervescent granules should be used with care in patients suffering from renal insufficiency.

Concomitant use of **ALKAFIZZ** effervescent granules with an antacid by patients with compromised renal function may result in the absorption of dangerously high amounts of aluminium (see **"INTERACTIONS"**).

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

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

INTERACTIONS:
Antacids:
Concomitant use of **ALKAFIZZ** effervescent granules with an antacid by patients with compromised renal function may result in the absorption of dangerously high amounts of aluminium (see **"WARNINGS"**).

Co-administration of antacids with citrates, such as contained in **ALKAFIZZ**, may result in systemic alkalosis, while concurrent administration of antacids with sodium citrate and sodium bicarbonate may lead to the development of calcium stones in patients with uric acid stones. It may also cause hypernatraemia.

Quinolones:
The sodium citrate in **ALKAFIZZ** may reduce the solubility of quinolone antibiotics, such as ciprofloxacin, norfloxacin, or ofloxacin, in the urine. Patients should therefore be monitored for signs of crystalluria and nephrotoxicity.

Salicylates:
Co-administration of salicylates with the sodium citrate in **ALKAFIZZ** may increase urinary excretion and reduce therapeutic effects of salicylates as a result of urinary alkalinisation.

Tetracyclines:
Due to an increase in intragastric pH, the absorption of tetracyclines may be decreased when it is co-administered with sodium bicarbonate. **ALKAFIZZ** should therefore not be taken within 1 to 2 hours of tetracycline administration.

Ketoconazole:
Since the sodium bicarbonate in **ALKAFIZZ** may increase gastrointestinal pH, the absorption of ketoconazole may be markedly reduced with concurrent administration. Patients should wait at least 2 hours before taking **ALKAFIZZ** following ketoconazole administration.

Methenamine:
ALKAFIZZ effervescent granules should not be administered with urinary tract antiseptics which require acidic urine, such as methenamine mandelate and methenamine hippurate (see **"CONTRA-INDICATIONS"**).

PREGNANCY AND LACTATION:
Pregnancy:
No studies have examined the effects of citrates on pregnancy.

Lactation:
Caution should be exercised when **ALKAFIZZ** is administered to a nursing mother.

DOSAGE AND DIRECTIONS FOR USE:
Adults:
One to two medicine measures (4 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 **"SIDE-EFFECTS AND SPECIAL PRECAUTIONS"**).

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

Children (6 - 12 years):
One 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 **"SIDE-EFFECTS AND SPECIAL PRECAUTIONS"**).

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Side-effects:
Metabolism and nutrition disorders:
Less frequently: Increased thirst and hypernatraemia (dizziness, fast heartbeat, high blood pressure, irritability, muscle twitching, restlessness, seizures, swelling of feet or lower legs, weakness) have been reported.
The following side-effects have been reported and frequencies are unknown:
Excessive administration of **ALKAFIZZ** effervescent granules may lead to metabolic alkalosis in patients with impaired renal function. Symptoms may include shortness of breath, muscle weakness and mental disturbances, such as restlessness, convulsions and coma.
Excessive doses may lead to sodium overloading and hyperosmolality with resulting oedema and possible effects on the cerebral, pulmonary or peripheral circulations.

Gastrointestinal system disorders:
Less frequent: Stomach cramps and laxative effect (diarrhoea or loose bowel movements) have been reported.
The following side-effects have been reported and frequencies are unknown:
Abdominal distension, flatulence, belching and nausea may occur if **ALKAFIZZ** effervescent granules are taken before effervescence is complete (see **"DOSAGE AND DIRECTIONS FOR USE"**).

Musculoskeletal and connective tissue disorders:
The following side-effects have been reported and frequencies are unknown:
Muscle hypertonicity, twitching and tetany may occur, especially in hypocalcaemic patients.

Special Precautions:
Caution is required in patients with peptic ulceration and renal abnormalities to avoid metabolic alkalosis. Patients with kidney disease should undergo periodic determinations of serum electrolytes to ensure that acid-base balance is maintained.

Patients on a sodium-restricted diet should not take **ALKAFIZZ**.

ALKAFIZZ should be taken with caution in patients with cirrhosis of the liver, congestive heart failure or hypertension, peripheral and pulmonary oedema and pre-eclampsia.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Refer to **"SIDE-EFFECTS AND SPECIAL PRECAUTIONS"**.
Treatment is symptomatic and supportive and consists mainly of correction of fluid and electrolyte balance. Consult a doctor in known cases of overdosage.

IDENTIFICATION:
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.

PRESENTATION:
ALKAFIZZ effervescent granules are available in clear glass bottles with a screw cap and a dosage measure or in plastic bottles with a screw cap and a dosage measure. Each bottle contains 60 g or 120 g effervescent granules.

Alternatively, **ALKAFIZZ** effervescent granules are available in individual 4 g sachets in packs of 8's or 30's.

STORAGE INSTRUCTIONS:
Store in a cool dry place, below 25°C.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
29/18.3/0378

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
CIPLA MEDPRO (PTY) LTD.
Rosen Heights
Pasita Street
Rosen Park
Bellville
7530
R.S.A.

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