SCHEDULING STATUS: **S0**

1. NAME OF MEDICINE:

CITRO-SODA granules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4 g contains:

Sodium bicarbonate	1 716 mg
Tartaric acid	858 mg
Citric acid	702 mg
Sodium citrate	613 mg

Contains sugar

Liquid glucose	356 mg

Contains Sweeteners

Saccharin sodium dihydrate	0,111 mg

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Sweetened, lemon flavoured granules. When added to water they effervesce and dissolve to form a clear, alkaline solution which is lemon flavoured.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications:

CITRO-SODA is a gastric antacid and urinary alkalinising agent.

As a urinary alkaliniser, **CITRO-SODA** can be used to alleviate symptoms associated with inflammatory conditions of the bladder. **CITRO-SODA** can be used to prevent crystalluria during sulphonamide treatment.

4.2. Posology and method of administration:

Posology

Do not exceed the prescribed dose.

Adults:

One to two 5 ml medicine measures (4 g to 8 g) in half a glass of cold water 3 to 4 times daily, taken on an empty stomach and followed with additional water.

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

Children (6 to 12 years of age):

One 5 ml medicine measure (4 g) in half a glass of cold water 2 to 3 times daily, taken on an empty stomach and followed with additional water.

Method of administration:

Drink after effervescence.

4.3. Contraindications:

CITROSODA GRANULES should not be used in patients with:

- Hypersensitivity to sodium bicarbonate, tartaric acid, citric acid, sodium citrate or any of the ingredients in the preparations.
- Patients with severe renal disease, metabolic disturbances with alkalosis, hypocalcaemia or hypochlorhydria.

CITRO-SODA should not be given with urinary antiseptics which require an acid urine, such as methenamine mandelate and methenamine hippurate (see **section 4.5**).

4.4. Special warnings and precautions for use:

Use with care in patients suffering from renal insufficiency.

Do not use this product if you are suffering from congestive cardiac failure or hypertension except under the advice and supervision of a doctor (see **section 4.8**).

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

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.

CITRO-SODA contains liquid glucose which may have an effect on the glycaemic control of patients with diabetes mellitus.

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.

Citric Acid:
Citric acid ingested frequently or in large quantities may cause erosion of the teeth and have a local irritant action.

Sodium bicarbonate:

Bicarbonate or bicarbonate-forming compounds should not be given to patients with respiratory alkalosis, hypocalcaemia, or hypochlorhydria.

Sodium-containing salts should be given with extreme caution to patients with heart failure, oedema, renal impairment, hypertension, eclampsia, or aldosteronism.

4.5. Interaction with other medicines and other forms of interactions:

Antacid*s*

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.

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. **CITRO-SODA** 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 **CITRO-SODA** 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 **CITRO-SODA** is not recommended.

Barbiturates

Alkalinisation of the urine leads to increased renal clearance of acidic medicines such as barbiturates.

Lithium

Sodium bicarbonate enhances lithium excretion.

4.6. Fertility, pregnancy and lactation:

Pregnancy:

The safety of **CITRO SODA** in pregnancy and lactation has not been established.

Lactation:

Caution should be exercised when administered to lactating mothers.

4.7. Effects on ability to drive and use machines:

None known.

4.8. Undesirable effects:

Frequency	System organ class	Undesirable effects
Less frequent	Gastrointestinal disorders	• Stomach cramps and laxative effect (diarrhoea or loose bowel movements).
	Metabolism and nutrition disorders	• Increased thirst • Hypernatremia (dizziness; fast heartbeat; high blood pressure; irritability; muscle twitching; restlessness; seizures; swelling of feet or lower legs; weakness).
Frequency unknown	Gastrointestinal disorders	• Abdominal distension, flatulence, belching and nausea may occur if the product is taken before effervescence is complete. • Violent vomiting, diarrhoea and abdominal pain may occur if product is ingested undiluted

	Metabolism and nutrition disorders:	• Metabolic alkalosis (shortness of breath, muscle weakness and mental disturbances such as: restlessness, convulsions and coma) may occur especially in patients with renal dysfunction. • Alkalosis may precipitate seizures. • Excessive doses may lead to sodium overloading and hyperosmolality. • Hypokalaemia (mood changes, tiredness, slow breathing, muscle weakness, and irregular heart-beat).
	Musculoskeletal and connective tissue disorders:	• Muscle hypertonicity, twitching and tetany may develop, especially in hypo-calcaemic patients.
	Cardiac disorder	• Cardiovascular collapse may occur if the product is ingested undiluted.
	Renal and urinary disorders	• Renal failure may occur if the product is ingested undiluted**.**

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

May also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com

4.9. Overdose:

Overdosage may result in metabolic alkalosis and hypernatraemia.

Alkalosis may precipitate seizures.

Excessive use of bicarbonate or bicarbonate-forming compounds may lead to hypokalaemia. Symptoms include mood changes, tiredness, slow breathing, muscle weakness, and irregular heartbeat.

Excessive use of Tartaric acid:
Strong solutions of tartaric acid are mildly irritant and if ingested undiluted may cause violent vomiting and diarrhoea, abdominal pain, and thirst. Cardiovascular collapse or acute renal failure may follow (see **section 4.8**).

Symptomatic and supportive treatment should be instituted to correct fluid and electrolyte balance with complete withdrawal of the preparation.

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

During treatment of acidosis, frequent monitoring of serum-electrolyte concentrations and acid–base status is essential.

5. PHARMACEUTICAL PROPERTIES

5.1. Pharmacodynamic properties:

A 18.3. Ion-exchange preparations

Mechanism of action:
CITRO-SODA has urinary alkalinising and gastric antacid 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. Pharmacokinetics 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:

Saccharin sodium dihydrate
Lemon Flavour TJA0455 (Alcohol (ethanol) and Flavour lemon oil terpene-less)
Glucose liquid (44 Baume)

6.2. Incompatibilities:

Not applicable

6.3. Shelf life:

24 Months

6.4. Special precautions for storage:

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

6.5. Nature and contents of container:

Screw-top, glass bottles containing 60 g, 100 g or 120 g and sachets of 4 g packed into cartons of 2's, 8's, 30's, 40's and 44's.

Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road,

Erand Gardens

Midrand,1685

Customer Care: 0860 ADCOCK /232625

8. REGISTRATION NUMBER:

E1031 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Old Medicine

10. DATE OF REVISION OF THE TEXT:

14 June 2023

Botswana: BOT9700041 S4 / BOT0200525 S4

Namibia: NS0 04/18/1254