1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

QUATRO-SODA CRANBERRY (Sodium bicarbonate 1716 mg, tartaric acid 858 mg, citric acid 702 mg, sodium citrate 613 mg, granules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Every 4 g of QUATRO-SODA CRANBERRY contains 1716 mg of sodium bicarbonate, 858 mg of tartaric acid, 702 mg of citric acid and 613 mg of sodium citrate. Excipients with known effect: Liquid glucose (spray-dried) 356 mg, sucrose 4,34 mg. For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Granules.

QUATRO-SODA CRANBERRY is pink to purple coloured granular powder with red to brown specks.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

QUATRO-SODA CRANBERRY is indicated:

- As a gastric antacid.
- As a urinary alkaliniser: to alleviate symptoms associated with inflammatory conditions of the bladder.
- 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 cold water 3 to 4 times daily, taken on an empty stomach and followed with additional water. Drink after effervescence.

Long-term therapy: One 5 ml medicine measure (4 g) daily (see section 4.8).

Special populations

Paediatric population

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. Drink after effervescence.

Method of administration

Oral use.

4.3. Contraindications

QUATRO-SODA CRANBERRY is contraindicated in:

- Patients with hypersensitivity to sodium bicarbonate, tartaric acid, citric acid, sodium citrate or to any of the excipients in QUATRO-SODA CRANBERRY (see section 6.1).
- Patients with metabolic disturbances with alkalosis, hypocalcaemia or hypochlorhydria.
- Patients taking urinary antiseptics which require an acid urine, such as methenamine mandelate, methenamine hippurate, hexamine mandelate or hexamine hippurate (see section 4.5).

- Patients with severe renal disease, renal failure or hypernatraemia.
- Patients with overt and occult cardiac failure.

4.4. Special warnings and precautions for use

Metabolic alkalosis

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 and acid-base balance to ensure that acid-base balance is maintained.

General

Caution should be observed in patients with cirrhosis of the liver, impaired renal function, congestive heart failure or hypertension, peripheral and pulmonary oedema and pre-eclampsia (see section 4.3)

Bacteriuria

Alkalinising medicines, such as QUATRO-SODA CRANBERRY, do not eradicate bacteriuria although they may temporarily relieve lower urinary tract symptoms.

Excipients

QUATRO-SODA CRANBERRY contains sucrose and glucose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with the rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take QUATRO-SODA CRANBERRY.

QUATRO-SODA CRANBERRY contains 613, 5 mg of sodium per 4 g, equivalent to 30 % of the WHO recommended daily intake of 2 g sodium for and adult.

4.5. Interaction with other medicines and other forms of interaction

Quinolones

Citrates, as in QUATRO-SODA CRANBERRY, may reduce the solubility of ciprofloxacin, norfloxacin or ofloxacin in the urine. Patients should be observed for signs of crystalluria and nephrotoxicity (see section 4.3).

Methenamine

Alkalinisation of the urine caused by sodium bicarbonate and citrates, as in QUATRO-SODA CRANBERRY, may reduce the effectiveness of methenamine by inhibiting its conversion to formaldehyde. Concurrent use with QUATRO-SODA CRANBERRY is contraindicated (see section 4.3).

Antacids

- Concurrent use of antacids with citrates, as in QUATRO- SODA CRANBERRY may result in systemic alkalosis.
- Concomitant administration of antacids with sodium citrate and sodium bicarbonate, as in QUATRO-SODA CRANBERRY, 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, as in QUATRO-SODA CRANBERRY, can increase aluminium absorption, possibly resulting in acute aluminium toxicity, especially in patients with renal insufficiency.

Salicylates

Concurrent use of salicylates with citrates, as in QUATRO-SODA CRANBERRY, may increase the urinary excretion and decrease the therapeutic effects of salicylates due to

alkalinisation of the urine.

Tetracyclines

Tetracycline absorption may be decreased when it is used concurrently with sodium bicarbonate, as in QUATRO-SODA CRANBERRY, because of the increase in intragastric pH. QUATRO-SODA CRANBERRY should not be taken within 1 to 2 hours of tetracyclines.

Alkalisation of the urine by QUATRO-SODA CRANBERRY may therefore result in a decreased therapeutic effect of tetracyclines.

Ketoconazole

Sodium bicarbonate, as in QUATRO-SODA CRANBERRY, may cause increased gastrointestinal pH; concurrent administration with QUATRO-SODA CRANBERRY, may result in a marked reduction in absorption of ketoconazole. Patients should take QUATRO-SODA CRANBERRY at least 2 hours after ketoconazole.

Lithium

Alkalisation of the urine by QUATRO-SODA CRANBERRY may result in a decreased therapeutic effect of lithium.

Amphetamines/ephedrine/pseudoephedrine

Alkalinisation of the urine due to the use of QUATRO-SODA CRANBERRY may result in an increased effect of amphetamines and ephedrine/pseudoephedrine.

Chlorpropamide

Alkalisation of the urine by QUATRO-SODA CRANBERRY may result in a decreased therapeutic effect of chlorpropamide.

Laxatives

Concurrent administration of citrates, as in QUATRO-SODA CRANBERRY, with laxatives may have an additive effect.

4.6. Fertility, pregnancy and lactation

Safety of QUATRO-SODA CRANBERRY in pregnancy and lactation has not been established.

Pregnancy

Studies regarding the effect of citrates, as in QUATRO-SODA CRANBERRY have not been done.

Breastfeeding

Caution should be exercised when administered to a nursing mother.

Fertility

No data available.

4.7. Effects on ability to drive and use machines

QUATRO-SODA CRANBERRY has negligible effect on the ability to drive or to use machines.

However, patients should be alerted to the risk of metabolic alkalosis which could cause mental disturbances and hypernatraemia, which could cause dizziness.

Patients should therefore not drive, use machinery or perform any tasks that require concentration, until they are certain that QUATRO-SODA CRANBERRY does not adversely affect their ability to do so (see section 4.8).

4.8. Undesirable effects

a) Tabulated list of adverse reactions

System organ class	Less frequent	Frequency unknown
Metabolism and nutrition disorders	Increased thirst, hypernatraemia (dizziness, fast heartbeat, high blood pressure, irritability, muscle twitching, restlessness, seizures, swelling of feet or lower legs, weakness)	Metabolic alkalosis (shortness of breath, muscle weakness and mental disturbances such as restlessness, convulsions and coma) especially in patients with renal dysfunction. Excessive doses may lead to sodium overloading, hyperosmolality
Gastrointestinal disorders	Stomach cramps, laxative effect (diarrhoea or loose bowel movements).	Abdominal distension, flatulence, belching, nausea (may occur if the QUATRO-SODA CRANBERRY is taken before effervescence is complete see section 4.2);
Musculoskeletal and connective tissue disorders		Muscle hypertonicity, twitching, tetany (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. Healthcare providers are asked to report any suspected adverse reactions to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

4.9. Overdose

Symptoms

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

Treatment

Symptomatic and supportive treatment should be instituted to correct fluid and electrolyte balance with complete withdrawal of QUATRO- SODA CRANBERRY. In these cases, regular electrolyte estimations should be taken, and the necessary therapy instituted.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Category and class: A 18.3. Ion-exchange preparations

Pharmacotherapeutic group: Other urologicals ATC code: G04BX

Mechanism of action

QUATRO-SODA CRANBERRY 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 an alkaline urine, the actual dissolution of uric acid stones may be accomplished.

Gastric antacid: Sodium bicarbonate, sodium citrate and citric acid react chemically to neutralise 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

Absorption

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.

Biotransformation

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

Elimination

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 excreted unchanged in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Acacia gum, cranberry flavour, liquid glucose (spray-dried), nature-identical flavouring substances, natural flavouring substances, neelicol purple (C.I. No. 11357), potato maltodextrin, sucrose and triacetin.

Contains sugar: Liquid glucose (spray-dried) 356 mg, sucrose 4,34 mg.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months.

In-use shelf life of high density polyethylene bottle packs: 30 days.

6.4. Special precautions for storage

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

Keep tightly closed.

Store in the original packaging until required for use.

6.5. Nature and contents of container

4 g is packed in triple laminate foil sachets.

30 sachets are packed in an outer cardboard carton.

60 g and 120 g is packed in a white high density polyethylene bottle with white opaque polypropylene cap with heat seal lining.

Not all packs and pack sizes are necessarily marketed.

6.6. Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

8. REGISTRATION NUMBER

54/18.3/0663

9. DATE OF FIRST AUTHORISATION

14 February 2023

10. DATE OF REVISION OF TEXT

14 February 2023

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