PROFESSIONAL INFORMATION FOR

ALKAFIZZ MIXED BERRY

SCHEDULING STATUS

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PROPRIETARY NAME (AND DOSAGE FORM):

ALKAFIZZ MIXED BERRY (Effervescent Granules).

COMPOSITION

Each medicine measures (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)	0,252 mL

Other excipients are mixed berry flavour and liquid glucose.

PHARMACOLOGICAL CLASSIFICATION

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

PHARMACOLOGICAL ACTION

ALKAFIZZ MIXED BERRY effervescent granules have urinary alkalising as well as gastric antacid properties.

Pharmacodynamic properties

Urinary alkaliniser

Sodium bicarbonate raises the urinary pH, by increasing the excretion of free bicarbonate ions in the urine. The actual dissolution of uric acid stones may be accomplished by maintaining an alkaline urine. Citrates (citric acid and sodium citrate) are metabolised to bicarbonates (see above).

Gastric antacid

Sodium bicarbonate, citric acid and sodium citrate 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.

Pharmacokinetic properties

Sodium bicarbonate

Sodium bicarbonate undergoes renal elimination. The carbon dioxide ($CO_{2)}$ that is formed is eliminated via the lungs.

Sodium citrate and citric acid

In the body, citrates are oxidised to form sodium bicarbonate, which is eliminated via the urine. Less than 5 % is excreted unchanged.

Tartaric acid

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

INDICATIONS

ALKAFIZZ MIXED BERRY is a gastric antacid and urinary alkalinising agent. As a urinary alkaliniser, ALKAFIZZ MIXED BERRY can be used to alleviate symptoms associated with

inflammatory conditions of the bladder. ALKAFIZZ MIXED BERRY can be used to prevent crystalluria during sulphonamide treatment.

CONTRAINDICATIONS

ALKAFIZZ MIXED BERRY is contraindicated:

- in patients with hypersensitivity to sodium bicarbonate, citric acid, sodium citrate, tartaric acid or any of the excipients in ALKAFIZZ MIXED BERRY.
- in patients with severe renal disease and metabolic disturbances with alkalosis, hypocalcaemia or hypochlorhydria.
- when co-administered with urinary tract antiseptics which require acid urine, such as methenamine mandelate and methenamine hippurate (see "**INTERACTIONS**").

WARNINGS AND SPECIAL PRECAUTIONS

In patients suffering from renal insufficiency, ALKAFIZZ MIXED BERRY effervescent granules should be used with caution.

Alkalinising agents may temporarily relieve lower urinary tract symptoms but they do not eliminate bacteriuria.

In patients with comprised renal function, concurrent use of ALKAFIZZ MIXED BERRY effervescent granules with an antacid may result in the absorption of dangerously high amounts of aluminium (see "**INTERACTIONS**").

Patients that suffer from hypertension and congestive cardiac failure should not use ALKAFIZZ MIXED BERRY effervescent granules, except under the advice and supervision of a doctor.

To avoid the condition of metabolic alkalosis, patients with renal abnormalities and patients with peptic ulceration should use ALKAFIZZ MIXED BERRY with caution. To ensure that acid-base balance is maintained, patients with renal disease should have periodic determinations of serum electrolytes.

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

In patients with cirrhosis of the liver, pre-eclampsia, peripheral and pulmonary oedema caution should also be taken.

Effects on ability to drive and use machines

None known.

INTERACTIONS

ALKAFIZZ MIXED BERRY effervescent granules should not be administered with urinary tract antiseptics which require acid urine, such as methenamine hippurate and methenamine mandelate (see "**CONTRAINDICATIONS**").

Antacids

Systemic alkalosis may occur with concurrent use of antacids and citrates. In patients with uric acid stones, simultaneous administration of antacids with sodium bicarbonate and sodium citrate may promote the development of calcium stones and may also cause hypernatraemia.

Concomitant use of citrate salts in ALKAFIZZ MIXED BERRY effervescent granules with aluminium-containing antacids, especially by patients with comprised renal function, may result in the absorption of dangerously high amounts of aluminium (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

Quinolones

The solubility of ciprofloxacin, norfloxacin, or ofloxacin in the urine may be reduced by citrates. Patients should be monitored for signs of nephrotoxicity and crystaluria.

Salicylates

Simultaneous use of salicylates with citrates may decrease the therapeutic effects of salicylates by increasing the urinary excretion of salicylates due to urine alkalinisation.

Tetracyclines

Due to the increase in intragastric pH, a decrease in tetracycline absorption may occur when it is used simultaneously with sodium bicarbonate. ALKAFIZZ MIXED BERRY should not be taken within 1 to 2 hours of tetracyclines.

Ketoconazole

Simultaneous use with sodium bicarbonate may result in a marked reduction in absorption of ketoconazole due to the increased gastrointestinal pH caused by sodium bicarbonate. Patients should take ALKAFIZZ MIXED BERRY at least 2 hours after ketoconazole.

Methenamine

Sodium bicarbonate and citrates alkalinises the urine, which may inhibit the conversion of methenamine to formaldehyde, resulting in a reduction of efficacy; simultaneous use with ALKAFIZZ MIXED BERRY is therefore not recommended.

PREGNANCY AND LACTATION

Pregnancy

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

Lactation

Caution should be exercised when administered to a breastfeeding mother.

DOSAGE AND DIRECTIONS FOR USE

Adults

One to two 5 mL medicine measures (4 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 (see "**SIDE EFFECTS"**).

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

Children (6 to 12 years)

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

SIDE 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 impairment. Excessive doses may lead to sodium overloading and hyperosmolality.

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 MIXED BERRY 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.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Overdosage may result in hypernatraemia and metabolic alkalosis (see "**SIDE EFFECTS**").

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.

Electrolyte estimations should be taken regularly and the necessary treatment provided.

IDENTIFICATION

White to straw-coloured granules with a berry odour and a sweet mixed berry taste.

After reconstitution with water, a clear to straw coloured solution with a berry odour and a sweet mixed berry taste is obtained.

PRESENTATION

ALKAFIZZ MIXED BERRY effervescent granules are available in round clear glass bottles with a white screw cap and a dosage measure, packed in an outer carton.

Each bottle contains 60 g or 120 g effervescent granules.

STORAGE INSTRUCTIONS

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

Do not refrigerate or freeze.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

45/18.3/0183

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