PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

CITRO-SODA CRANBERRY Granules

Each 4 g of granules contains:

Sodium bicarbonate	1716 mg
Tartaric acid	858 mg
Citric acid	702 mg
Sodium citrate	613 mg

Contains sugar :

Liquid glucose	356 mg

Contains Sweeteners :

Aspartame	10 mg

Read all of this leaflet carefully because it contains important information for you.
CITRO-SODA CRANBERRY granules is available without a doctor's prescription for you to treat a mild illness. Nevertheless, you still need to use **CITRO-SODA CRANBERRY** granules carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your health care provider or pharmacist if you need more information or advice.
- Do not share **CITRO-SODA CRANBERRY** granules with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What **CITRO-SODA CRANBERRY** is and what it is used for.
2. What you need to know before you take **CITRO-SODA CRANBERRY**.
3. How to take **CITRO-SODA CRANBERRY**.
4. Possible side effects.
5. How to store **CITRO-SODA CRANBERRY**.
6. Contents of the pack and other information.

1. What CITRO-SODA CRANBERRY is and what it is used for

- **CITRO-SODA CRANBERRY** is a gastric antacid (neutralises excess acid in the stomach) and urinary alkalinising agent.
- **CITRO-SODA CRANBERRY** can be used to alleviate symptoms of inflammatory conditions of the bladder.
- It can also be used to prevent crystalluria (formation of crystals in urine) during sulphonamide (antibiotic) treatment.

2. What you need to know before you take CITRO-SODA CRANBERRY

Do not take CITRO-SODA CRANBERRY:

- If you are hypersensitive (allergic) to sodium bicarbonate, tartaric acid, citric acid, Sodium citrate or any of the other ingredients of **CITRO-SODA CRANBERRY**.
- If you suffer from severe renal (kidney) disease.
- If you suffer from metabolic disturbances like alkalosis blood. (rise in alkali level in the blood), hypocalcaemia (low calcium levels) or hypochlorhydria (low chloride levels)
- If you are taking urinary antiseptics which require an acidic urine, such as methenamine mandelate and methenamine hippurate.
- If you are on a special diet (if you have to limit the amount of sodium that you eat)

Warnings and precautions

CITRO-SODA CRANBERRY may cause problems if you suffer from phenylketonuria (type of protein deficiency).

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

Taking frequent and large quantities of **CITRO-SODA CRANBERRY** may cause erosion of the teeth and have a local irritant action.

CITRO-SODA CRANBERRY should not be given to patients with

- Respiratory alkalosis (rapidly increased breathing that changes the pH in the blood).
- Hypocalcaemia (low level of calcium in the blood).
- Hypochlorhydria (absent or low production of hydrochloric acid in the stomach).

CITRO-SODA CRANBERRY should be taken with care if you have any of the following:

- Renal insufficiency and renal abnormalities (kidney problems)
- Congestive cardiac (heart) failure
- Hypertension (high blood pressure)
- Peptic ulcers (stomach ulcers)
- Liver cirrhosis (liver damage)
- Oedema (fluid accumulation) in the lungs or limbs.
- Pre-eclampsia (a type of pregnancy complication)
- Aldosteronism (a condition in which there is excessive secretion of a hormone aldosterone, which disturbs the balance of sodium, potassium, and water in the blood and so leads to high blood pressure.)
- If you are on a special diet (if you have to limit the amount of sodium that you eat).

Children and adolescents

CITRO-SODA CRANBERRY is for use in children between the ages of 6 to 12 years old. **(see Section 3 "How to take CITRO-SODA CRANBERRY"**)

Other medicines with CITRO-SODA CRANBERRY:

Always tell your health care professional if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Please consult your doctor, pharmacist or other health care professional if you want to use **CITRO-SODA CRANBERRY** but are taking the following medicines:

- Antacids (medicines that neutralize stomach acid)
- Quinolones (a type of antibiotic)
- Salicylates (medicines class use for relief of pain, fever and inflammation)
- Barbiturates (acts as a central nervous system depressant)
- Lithium (a type of medicine known as a mood stabiliser).

Do not take CITRO-SODA CRANBERRY if you are using a medicine containing methenamine (a medicine used to treat infection of the urinary tract).

If you are taking any of the following medicines, **CITRO-SODA CRANBERRY** must only be taken at least 2 hours after these medicines:

- Tetracyclines (a type of antibiotic)
- Ketoconazole (an anti-fungal agent).

CITRO-SODA CRANBERRY with food and drinks

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

Pregnancy, breastfeeding and fertility

The safety of this formulation during pregnancy and breastfeeding has not been established. Caution should be exercised when administered during breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking **CITRO-SODA CRANBERRY**.

Driving and using machinery

None known.

It is not always possible to predict to what extent **CITRO-SODA CRANBERRY** may interfere with the daily activities of a patient. Patients should ensure that that they do engage in tasks or activities requiring mental alertness ,judgement or sound coordination until they are aware of the measure to which **CITRO-SODA CRANBERRY** affects them.

CITRO-SODA CRANBERRY contains liquid glucose

This may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **CITRO-SODA CRANBERRY**.

CITRO-SODA CRANBERRY contains Aspartame. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU),a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. HOW TO TAKE CITRO-SODA CRANBERRY:

Always take **CITRO-SODA CRANBERRY** exactly as described in this leaflet or as your doctor or pharmacist have told you. You must check with your doctor or pharmacist if you are not sure.

Do not exceed the recommended dosage.

CITRO-SODA CRANBERRY :

Adults:

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

Drink the contents of the whole glass after effervescence (after the granules have stopped fizzing/bubbling in the glass).
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 of granules) in half a glass of cold water 2 to 3 times daily, taken on an empty stomach and followed with additional water.
Drink the contents of the whole glass after effervescence (after the granules have stopped fizzing/bubbling in the glass).

If you take more CITRO-SODA CRANBERRY than you should:

The following signs and symptoms may indicate that you have overdosed on this product:

- Metabolic alkalosis (rise in alkali level in blood)
- Alkalosis (blood alkalinity) that may precipitate seizures
- Hypernatraemia (too much sodium in the blood),
- Hypokalaemia (electrolyte abnormality) causing symptoms that include mood changes, tiredness, slow breathing, muscle weakness, and irregular heartbeat.

If large concentrations of tartaric acid (as contained in **CITRO-SODA CRANBERRY**) are ingested undiluted, it may cause violent vomiting and diarrhoea, abdominal pain, and thirst. Cardiovascular collapse or acute renal failure may follow. See under '**POSSIBLE SIDE EFFECTS**'.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take CITRO-SODA CRANBERRY:

Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS:

CITRO-SODA CRANBERRY can have side effects.
Not all side effects reported for **CITRO-SODA CRANBERRY** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Stomach cramps
- laxative effect (diarrhoea or loose bowel movements)
- Increased thirst
- Hypernatraemia (too much sodium in the blood): dizziness; fast heartbeat; high blood pressure; irritability; muscle twitching; restlessness; seizures (a sudden attack, usually referring to contractions of muscles); swelling of feet or lower legs; weakness may occur.

Side effects with unknown frequency:

- Muscle hypertonicity, twitching and tetany may develop, especially in hypocalcaemic (the blood has too little calcium) patients.
- Metabolic alkalosis (rise in alkali level in blood): shortness of breath, muscle weakness and mental disturbances such as restlessness, convulsions and coma may occur especially in patients with renal dysfunction.
- Excessive doses may lead to sodium overloading (High sodium intake) and hyperosmolality (high sodium levels in the blood).
- Abdominal distension, flatulence (large amount of gas in stomach or intestine), belching (burping), and nausea may occur if the product is taken before effervescence is complete.
- Excessive doses may lead to hypokalaemia (electrolyte abnormality) causing systoms that include mood changes, tiredness, slow breathing, muscle weakness, and irregular heartbeat.
- **Citro-Soda Cranberry** granules are mildly irritant and if taken undiluted may cause violent vomiting and diarrhoea, abdominal pain, and thirst. Cardiovascular collapse or acute renal failure may follow**.**

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse.
You can report side effects to the Adcock Ingram Pharmacovigilance department by e-mail to Adcock.Aereports@adcock.com, fax to +27 86 553 0128 or call 011 635 0134.
You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform(who-umc.org) found on SAHPRA's website. By reporting side effects, you can help provide more information on the safety of **CITRO-SODA CRANBERRY**.

5. How to store CITRO-SODA CRANBERRY:

- Store all medicines out of the reach and sight of children.
- Store in a cool (at or below 25 °C), dry place.
- Keep in original packaging until required for use.
- Do not use after the expiry date stated on the label and carton.

6. Content of the pack and other information

What CITRO-SODA CRANBERRY contains:

Each 4 g of granules contains the following as active ingredients:

Sodium bicarbonate	1716 mg
Tartaric acid	858 mg
Citric acid	702 mg
Sodium citrate	613 mg

The other ingredients are:

Aspartame (E951), Colour blue F, D & C No.1 (C.I 42090), Colour carmoisine WS (C.I. 14720), Flavour Cranberry permaseal S-123772,Glucose Liquid (44 Baume).

What CITRO-SODA CRANBERRY looks like and contents of the pack.

CITRO-SODA CRANBERRY consists of sweetened, cranberry flavoured granules. When added to water they effervesce and dissolve to form a red violet coloured, alkaline solution which is cranberry flavoured.
Screw-top glass bottles contains 60 g, 100 g or 120 g and sachets contains 4 g packed into cartons of 2's, 8's, 30's and 44's.

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