PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE – Health Supplement
This unregistered medicine has not been evaluated by the South African Health Product Regulatory Authority for its safety, quality or intended use.

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

Saltabs Fizzy (electrolyte replacement), effervescent tablet.

2. QUALITIVE AND QUANTITIVE COMPOSITION

Sodium Bicarbonate	740.74 mg
providing Sodium (elemental)	200.00 mg
Potassium chloride	268.04 mg
providing Potassium (elemental)	150.00 mg
Magnesium oxide	169.49 mg
providing Magnesium (elemental)	100.00 mg
Calcium Carbonate	162.50 mg
providing Calcium (elemental)	65.00 mg
Manganese Amino Acid Chelate 10%	10.00 mg
providing Manganese (elemental)	1.00 mg
Thiamine (Vitamin B1)	0.30 mg
Riboflavin (Vitamin B2)	0.30 mg

Contains sweetener: Sucralose 30.00 mg
Sugar free.
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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Flat, round, white with orange specs effervescent tablets with a citrus flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Saltabs Fizzy contributes to the maintenance of normal electrolyte balance in anticipation of extended, high intensity exercise. Supports hydration before, during and after exercise and to maintain performance.

4.2 Posology and method of administration

Posology

Adults (18 years and older)

- Dissolve one effervescent tablet in 250 ml of water.
- Drink as required to quench thirst and replace fluid loss.
- Can be taken before, during or after exercise, or as directed by a healthcare practitioner.

Method of administration

For oral use.

4.3 Contraindications

Hypersensitivity to the active ingredients or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- Not to be used in cases of dehydration as a substitute of an oral rehydration solution.
- Increased sodium intake has been associated with worsening of the following conditions: osteoporosis, multiple sclerosis, cardiovascular disease, hypernatremia, hypertension, kidney disease with proteinuria. Patients should be advised to consume sodium in moderation.
- Kidney disease affects potassium excretion and increases the risk for elevated potassium levels. Caution should be advised for those with kidney disease (including chronic kidney disease), kidney failure or post-kidney transplant.
- The co-administration of calcium salts or thiazides may lead to developing hypercalcaemia. When indicated, serum calcium, phosphate, alkaline phosphatase, liver function tests and magnesium should be monitored.

- Use with caution in patients with established osteoporosis.
- Magnesium supplements can increase the risk of hypermagnesemia in those with reduced or impaired kidney function.

4.5 Interaction with other medicines and other forms of interaction

Interaction with Medicines

- Concomitant use of ACE inhibitors and angiotensin receptor blocks with high doses of potassium increase the risk of hyperkalaemia.
- Concomitant use of potassium-sparing diuretics with potassium supplements increases the risk of hyperkalaemia.
- Concomitant use of mineralocorticoids and some glucocorticoids, didanosine, sodium phosphates and tolvaptan with sodium may increase the risk of hypernatremia.
- High sodium intake can reduce plasma concentration of lithium by increasing lithium excretion. Patients taking lithium should avoid significant alterations in their dietary/ supplementary intake of sodium.
- Calcium and magnesium can decrease absorption of bisphosphonates, tetracyclines, quinolones and gabapentin.
- Taking calcipotriene with calcium may increase the risk of hypercalcaemia.
- Calcium may reduce levels of dolutegravir, elvitegravir and raltegravir.
- Calcium carbonate supplements reduce effectiveness of levothyroxine in those with hypothyroidism when taken concomitantly.
- Calcium appears to reduce the absorption of sotalol when taken concomitantly.
- Magnesium can reduce the bioavailability of levodopa/carbidopa.

Interactions with Diseases / Impairments

- Saltabs Fizzy and use in Haemophiliacs and patients scheduled for surgery are advised to discontinue use at least 2 weeks before elective surgical procedures (see section 4.4).

Interactions with Food

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting Saltabs Fizzy
- Taking magnesium-containing supplements with food may reduce the risk of diarrhoea.

4.6 Fertility, pregnancy and lactation

<u>Women of childbearing potential / Contraception in males and females</u>

No information available.

Pregnancy

Safety during pregnancy has not been established.

Breastfeeding

Safety during breastfeeding has not been established.

Fertility

No information available.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that Saltabs Fizzy does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal disorders:
Frequency unknown: nausea, vomiting, abdominal pain, diarrhoea, flatulence.

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 professionals are asked to report any suspected adverse reactions to SAHPRA via the "Report Drug Reaction Process", found online under SAHPRA's safety publications: https://www.sahpra.org.za/

4.9 Overdose

In overdose, side effects can be precipitated or be of increased severity (see section 4.8). Treatment of overdose is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category of medicine D Complementary Medicines: Health Supplements 34.12 Multiple substance formulation

Saltabs Fizzy contributes to the maintenance of normal electrolyte balance in anticipation of extended, high intensity exercise. Supports hydration before, during and after exercise and to maintain performance.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on Saltabs Fizzy.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Citric Acid
- Colourant (E110)
- Flavour
- Isomalt
- Polyethylene glycol 6000
- Silicon dioxide
- Sucralose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

- Store at or below 25 °C.
- Protect from moisture.
- Store in the original container.
- Do not use after the expiry date stated on the label.
- Return all unused Saltabs Fizzy to your pharmacist.
- Do not dispose of unused Saltabs Fizzy in drains or sewerage systems (e.g. toilets).

6.5 Nature and contents of container

The effervescent tablets are available in 10’s in a printed tube with a white lid, packed into outer carton.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

No special requirements.

7. THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Crux Pharmaceuticals (Pty) Ltd
630 Jacqueline Drive
Garsfontein
Pretoria
0042

Marketed by:
Cedarpharm (Pty) Ltd
3798 Jan Frederick Ave
Randpark Ridge
Randburg
2169

8. REGISTRATION NUMBER

To be allocated.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be determined.

10. DATE OF REVISION OF TEXT

October 2023