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BIOGEN
FOR THE RESULTS YOU WANT

ELECTROLYTE + FIZZY

PROFESSIONAL INFORMATION

D 34.12 Multiple Substance Formulation. Complementary Medicine: Health Supplement.
Health supplements are intended only to complement health or supplement the diet.

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.
Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

BIOGEN ELECTROLYTE + FIZZY (Effervescent tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each BIOGEN ELECTROLYTE + FIZZY Effervescent tablet contains:

Sodium (as Sodium Chloride, Trisodium Citrate and Sodium Bicarbonate)	438 mg
Potassium (as Potassium Chloride)	132 mg
Magnesium (as Magnesium Citrate and Magnesium Oxide)	125 mg
Calcium (as Calcium Carbonate)	31 mg
Ascorbic Acid (Vitamin C)	15 mg
Vitamin B_1 (as Thiamine Hydrochloride)	0,3 mg
Riboflavin (Vitamin B_2)	0,3 mg

Contains sugar: dextrose (1000 mg) and isomalt (300 mg) per effervescent tablet.
Contains sweetener: acesulfame-K and sucralose blend (34,5 mg) per effervescent tablet.
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Effervescent tablets.
Flat, round, bevelled-edged effervescent tablets with a citrus flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BIOGEN ELECTROLYTE + FIZZY contributes to normal electrolyte balance and normal muscle function.

4.2 Posology and method of administration

Adults (18 years and older)

- Dissolve one effervescent tablet in 500 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.

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

- 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

Interactions 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

- BIOGEN ELECTROLYTE + 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 BIOGENELECTROLYTE + FIZZY.
- Taking magnesium-containing supplements with food may reduce the risk of diarrhea.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

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 BIOGEN ELECTROLYTE + FIZZY does not adversely affect their performance.

4.8 Undesirable effects

4.8 a Summary of adverse reactions

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

4.8 b Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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.*

4.9 Overdose

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity.
Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

D 34.12 Multiple Substance Formulation.

5.1 Pharmacodynamic properties

- BIOGEN ELECTROLYTE + FIZZY contributes to normal electrolyte balance and normal muscle function.

5.2 Pharmacokinetic properties

- Pharmacokinetic studies have not been conducted on BIOGEN ELECTROLYTE + FIZZY.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Sodium bicarbonate
- Citric acid anhydrous
- Dextrose
- Isomalt
- Tartaric acid
- Sucralose/Acesulfame-K blend
- Polyethylene glycol
- Polyvinylpyrrolidone
- Flavouring
- Colourant

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 Months.

6.4 Special precautions for storage

- Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN.
- Store in the original container and keep the container tightly sealed.
- Do not use after the expiry date stated on the label.
- Return all unused BIOGEN ELECTROLYTE + FIZZY to your pharmacist.
- Do not dispose of unused BIOGEN ELECTROLYTE + FIZZY in drains or sewerage systems (e.g. toilets).

6.5 Nature and contents

Plastic tubes of 10 effervescent tablets, with a desiccant cap, packed into an outer carton.
Pack size: 10 or 30 effervescent tablets.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Manufactured for the Dis-Chem Group
23 Stag Road, Glen Austin, Johannesburg, South Africa
careline@dischem.co.za
0860 347 243
www.dischem.co.za

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.