

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**SCHEDULING STATUS: S0**

**PROPRIETARY NAME (and dosage form): ALPHA Rehydration Effervescent Tablets 10's**

**ACTIVE INGREDIENTS:**

Each effervescent tablet contains: mg \*%NRV

Magnesium Amino Acid Chelate  
providing Magnesium (elemental) 700mg  
140mg 41%

Potassium Chloride  
providing Potassium (elemental) 335.05 mg  
174.266 mg \*\*\*

Sodium Chloride  
•providing sodium (elemental) 158 mg  
39.322 mg 2%

Sodium bicarbonate  
•providing sodium (elemental) 900 mg  
252 mg 13%

Calcium Carbonate  
•providing Calcium (elemental) 77.5 mg  
31 mg 2.50%

Ascorbic Acid (Vitamin C) 50 mg 50%

Thiamine HCl (Vitamin B1)  
providing Thiamine (elemental) 410 mcg  
340 mcg 28%

Riboflavin (Vitamin B2) 300 mcg 23%

\*NRV (Nutrient Reference Values)

\*\*\* %NRV supplied is negligible

Contains Sweeteners: Sucralose 20 mg per effervescent tablet

Excipients: Litchi flavour (50mg) and a proprietary effervescent blend (2904 mg).

The effervescent blend contains citric acid, polyethylene glycol, isomalt, Sucralose, silicon dioxide

Complementary Medicine, Health Supplement

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use

Read all of this leaflet carefully because it contains important information for you.

Keep this leaflet. You may need to read it again.

ALPHA Rehydration is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use ALPHA Rehydration carefully to get the best results from it.

Do not share ALPHA Rehydration with any other person.

Ask your healthcare provider or Pharmacist if you need more information or advice.

What is in this leaflet?

1. What ALPHA Rehydration is, and what it is used for
2. What you need to know before you take ALPHA Rehydration
3. How to take ALPHA Rehydration
4. Possible side effects
5. How to store ALPHA Rehydration
6. Contents of the pack and other information

1. What ALPHA Rehydration is, and what it is used for

Water is the foundation of life. All human cells comprise of between 75% - 85% water. The water balance is maintained by the kidneys through a fine equilibrium between electrolytes (minerals) such as sodium, potassium, magnesium and calcium. During periods of intense exercise, hot weather, illness, stress and other factors, the body may easily become dehydrated (defined as a loss of 1% of body weight in water) and lose large amounts of electrolytes. ALPHA Rehydration is designed to assist in improving recovery after strenuous exercise and maintaining the levels of electrolytes required for optimum hydration and nerve and muscle function (including helping to prevent cramps) on a daily basis.

**Magnesium**

Magnesium is an important factor required for healthy tissue formation, and especially bones and teeth. In addition, Magnesium is also an essential contributor to normal muscle function and in maintaining good overall metabolism and health. When exercising, Magnesium helps to provide sufficient oxygen, increase energy production, strength and stamina in the muscles.

**Potassium**

Potassium contributes to the normal function of muscles and the maintenance of normal blood pressure. Perspiration causes the loss of significant amounts of potassium which may contribute to the fatigue experienced after endurance exercise. Potassium also plays a key role in maintaining optimal hydration in the cells, as it is the major electrolyte in the intra-cellular fluid.

**Sodium**

Sodium contributes to the normal function of muscles and helps to prevent dehydration. Sodium is the major electrolyte in the extra-cellular fluid. During extensive exercise or perspiration, significant amounts of sodium may be lost.

**Calcium**

Calcium contributes to the maintenance of bones and teeth. It is also an electrolyte which is vital to the function of muscles and nerves and particularly the heart. During intense exercise or periods of high stress or heat, perspiration may lead to excessive loss of calcium.

**Vitamin C**

Vitamin C (ascorbic acid) is an anti-oxidant protecting organs, cells and blood vessels from free-radical damage. It helps to build and protect collagen in connective tissue, bones, teeth and skin. It also contributes to improved absorption of fats, proteins and iron from food while combatting fatigue and lack of energy.

**Vitamin B1**

Vitamin B1 helps to metabolise carbohydrates, fats and proteins, and is essential for the production of energy. It may also assist in reducing lactic acid formation during exercise.

**Vitamin B2**

Vitamin B2 is a factor in the maintenance of good health. It helps to protect and optimize the energy-producing mechanisms of the cell. People who exercise regularly therefore generally require more Vitamin B2 on a daily basis.

2. What you need to know before you take ALPHA Rehydration

Do not take ALPHA Rehydration:

- if you are hypersensitive (allergic) to any of the ingredients of ALPHA Rehydration (listed in section 6).
- if you are using Potassium-sparing diuretics (due to the Potassium content of ALPHA Rehydration).
- if you suffer from Hemochromatosis (due to the Vitamin C content of ALPHA Rehydration).
- if you suffer from a Kidney condition (due to the Magnesium AAC content of ALPHA Rehydration).

**Warnings and precautions**

Keep out of reach of children.

Unless otherwise prescribed, do not exceed the stated daily dose.

If you suffer from Hypertension please consult your healthcare practitioner before using ALPHA Rehydration (due to the Chloride content of ALPHA Rehydration, which may exacerbate high blood pressure)

Vitamin supplements should not replace a balanced diet.

**Other medicines and ALPHA Rehydration**

Always tell your healthcare provider if you are taking any other medicine.

Magnesium may interfere with the action of certain antibiotics.

Magnesium may interfere with medication for heart failure, osteoporosis, HIV or Paget's Disease.

**ALPHA Rehydration with food**

Vitamin C may increase the absorption of iron from food.

**Pregnancy and 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 healthcare provider for advice before taking this medicine.

Safety in pregnancy has not been established.

3. How to take ALPHA Rehydration

Do not share medicines prescribed for you, with any other person.

Take ALPHA Rehydration exactly as described in this leaflet or as prescribed by your Doctor or Pharmacist.

**Dosage and Directions for use**

Adults and Children over 4 years of age: Take ONE effervescent tablet daily after exercise or as prescribed by your Doctor or Pharmacist. (Dissolve tablet in a glass of water and drink).

Do not exceed the stated daily dosage.

If you take more ALPHA Rehydration than you should you may experience diarrhoea or nausea, muscle cramps, tiredness

In the event of overdosage, consult your Doctor or Pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ALPHA Rehydration, do not take a double dose to make up for forgotten doses.

4. Possible side effects

ALPHA Rehydration can have side effects.

Not all side effects reported for ALPHA Rehydration are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ALPHA Rehydration, please consult your healthcare provider for advice.

If any of the following happens, stop taking ALPHA Rehydration and tell your doctor:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching.
- Diarrhoea, nausea, stomach pain or upset stomach

5. How to store ALPHA Rehydration

Store all medicines out of reach of children.

- Store in a cool, dry place below 25°C .
- Keep lid firmly closed to exclude moisture
- Use within 30 days of opening.

6. Contents of the pack and other information

What ALPHA Rehydration contains

• The active substances are Magnesium Amino Acid Chelate (700 mg), Potassium Chloride (335.05 mg), Sodium Chloride (158 mg), Sodium Bicarbonate (900mg), Calcium Carbonate (77,5 mg), Vitamin C (50mg), Thiamine HCl (410 mcg) and Riboflavin (300 mcg)

• The other ingredients are Litchi Flavour (50mg) and a proprietary effervescent blend (2904mg)

The effervescent blend contains: citric acid, polyethylene glycol, isomalt, Sucralose, silicon dioxide

What ALPHA Rehydration looks like and contents of the pack

- White cylindrical effervescent tablet.
- 10 effervescent tablets in a polypropylene tube.

**Applicant**

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