Professional information for SALTABS DAY

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT (WESTERN HERBAL MEDICINE / HEALTH SUPPLEMENT)

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

SCHEDULING STATUS

S0

1 NAME OF THE MEDICINE

SALTABS DAY tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Sodium Chloride	200 mg
Potassium Chloride	15 mg
Magnesium oxide	25 mg
Dextrose	100 mg
Calcium Carbonate	15 mg

Excipients with known effects:

Contains sugar (12,65 mg lactose monohydrate per tablet).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

White round tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

SALTABS DAY contributes to the maintenance of normal electrolyte balance by replacing minerals which was lost during the day after extended, high intensity exercise.

4.2 Posology and method of administration

Adults:

- Take 1 – 2 tablets with a full glass of water 3 times a day or as required during endurance exercise.

Children:

Not suitable for children under the age of 18 years.

4.3 Contraindications

Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 2 or 6.1.

4.4 Special warnings and precautions for use

Cardiovascular disorders:

SALTABS DAY should be used with caution in patients with cardiovascular disorders such as hypertension.

Kidney disorders:

SALTABS DAY may worsen kidney disfunction in patients with existing kidney disease. Use with caution.

Contains sugar

SALTABS DAY contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption should not take SALTABS DAY.

Contains sodium

SALTABS DAY contains 78,6 mg sodium per tablet, equivalent to 4 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Paediatric population

SALTABS DAY is not suitable for children under the age of 18 years.

4.5 Interaction with other medicines and other forms of interaction

Antibiotic medicines:

Concomitant use of SALTABS DAY with antibiotics may reduce absorption. Doses should be separated by at least 2 hours prior, or 4 to 6 hours after taking SALTABS DAY

Levothyroxine:

Concomitant use of SALTABS DAY with levothyroxine may reduce absorption. Patients should be advised to take levothyroxine and SALTABS DAY at least 4 hours apart.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

SALTABS DAY is unlikely to affect the ability to drive a vehicle and use machines.
Caution is advised before driving a vehicle or operating machinery until the effects of SALTABS DAY are known.

4.8 Undesirable effects

SALTABS DAY is generally well tolerated.

Immune system disorders:

Frequency unknown: hypersensitivity and/or allergic reactions.

Metabolism and nutrition disorders:

Frequency unknown: loss of appetite.

Nervous system disorders:

Frequency unknown: headache.

Gastrointestinal disorders:

Frequency unknown: stomach upset, nausea, vomiting, abdominal pain, diarrhoea, belching, flatulence, constipation, heartburn.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of SALTABS DAY is important. It allows continued monitoring of the benefit/risk balance of SALTABS DAY. Health care providers are asked to report any suspected adverse reactions to the South African Health Products Regulatory Authority (SAHPRA) via the 6.04 Adverse Drug Reaction Reporting Form, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class:

D 33.7 Combination Product.

SALTABS DAY is a multi-vitamin/mineral supplement that contributes to the maintenance of normal electrolyte balance by replacing minerals which was lost during the day after extended, high intensity exercise.

5.2 Pharmacokinetic properties

Sodium is absorbed by the small intestines, distributed to extracellular compartments, and is excreted in the urine and sweat.

Magnesium is absorbed throughout the gastrointestinal tract, is distributed in the skeleton and soft tissue, and excreted in the urine.

Calcium absorption is affected by several factors like age, race, environmental and dietary conditions. Calcium is distributed in the bones and teeth and excreted via the urine and faeces.

Potassium in the body is regulated by the kidneys and distribution in intracellular and extracellular fluid influences serum potassium levels without changing the total body potassium. Potassium is excreted mainly in the urine.

Pyridoxine (Vitamin B_6) is passively absorbed from the upper gastrointestinal tract, converted in the liver to the coenzyme pyridoxal phosphate and excreted in the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal silicon dioxide,

crospovidone,

lactose monohydrate,

magnesium stearate,

povidone,

pregelatinised starch,

talc.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

Store at or below 25 °C.

6.4 Special precautions for storage

Protect from light and moisture.

6.5 Nature and contents of container

A white container containing 30/60 tablets, packed inside a carton.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Crux Pharmaceuticals

630 Jacqueline Dr

Garsfontein

Pretoria

0042

Marketed by:

Cedarpharm (Pty) Ltd

3798 Jan Frederick Drive

Randpark Ridge

2169

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

This leaflet was last revised in August 2022.