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 NIGHT tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Matricaria chamomilla L. (Chamomile) powder	100 mg
Sodium chloride	200 mg
providing Sodium	78,6 mg
Magnesium oxide	100 mg
providing Magnesium (elemental)	60,3 mg
Calcium carbonate	15 mg
providing Calcium (elemental)	6 mg
Potassium chloride	15 mg
providing Potassium	7,86 mg
Pyridoxine (Vitamin B_6)	5 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
Tablets.
Round, greyish brown tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
SALTABS NIGHT 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 after dinner or as required.
- Do not exceed a daily intake of 4 tablets.

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

Kidney disorders:
SALTABS NIGHT may worsen kidney disfunction in patients with existing kidney disease. Use with caution.

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

Contains sodium
SALTABS NIGHT 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 NIGHT 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 NIGHT with antibiotics may reduce absorption. Doses should be separated by at least 2 hours prior, or 4 to 6 hours after taking SALTABS NIGHT.

Levothyroxine:
Concomitant use of SALTABS NIGHT with levothyroxine may reduce absorption. Patients should be advised to take levothyroxine and SALTABS NIGHT 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 NIGHT 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 NIGHT are known.

4.8 Undesirable effects
SALTABS NIGHT 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 NIGHT is important. It allows continued monitoring of the benefit/risk balance of SALTABS NIGHT. 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 NIGHT 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 B6) 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 or 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 Avenue
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.