

PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE – Health supplement

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

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

Absolute B, capsules.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each capsule contains:

Thiamine hydrochloride	112,36 mg
providing Vitamin B ₁	88,40 mg
Vitamin B ₂ (Riboflavin)	25,00 mg
Calcium D-Pantothenate	20,00 mg
providing Vitamin B ₅	18,40 mg
Pyridoxine hydrochloride	121,51 mg
providing Vitamin B ₆	100,00 mg
Vitamin B ₁₂ (Cyanocobalamin) 0,2 %	0,10 mg

Sugar free

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

White veggie capsule

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

A Vitamin B formula, as contained in Absolute B, used as a nutritional supplement to help promote energy and support the central nervous system.

4.2 Posology and method of administration

Adults

One capsule daily, preferably taken one hour after meals. Do not exceed the stated dose.

The capsule should be swallowed whole with water.

Older people

In elderly patients no special dosage recommendations exist.

Patients with renal or hepatic impairment

In patients with renal or hepatic insufficiency no special dosage recommendations exist.

Paediatric population

Not recommended for children and adolescents

Method of administration

Oral use

4.3 Contraindications

Contraindicated in patients with an allergic hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

It is a supplement and is not intended for a specific vitamin deficiency.

4.4 Special warnings and precautions for use

Unless otherwise prescribed, do not exceed the stated dose. Do not use if suffering from a heart condition except under medical practitioner supervision.

Do not use with prediagnosed high blood pressure.

Do not take for longer than 4 weeks at a time.

4.5 Interaction with other medicines and other forms of interaction

None known at the recommended dosage.

4.6 Fertility, pregnancy, and lactation

Pregnancy and lactation

Do not use during pregnancy and lactation.

Fertility

For Absolute B no clinical data on the effects on fertility are available.

Safety in pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

4.7 Effects on ability to drive and use machines

Absolute B should not affect the ability of individuals to drive or operate machines.

4.8 Undesirable effects

Immune system disorders	<i>Frequency not known:</i> Hypersensitivity reaction (such as rash and pruritis)
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Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It follows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Alternatively contact Astral Pharma (Pty) Ltd. at 010 021 0750 or medical@astralpharma.co.za or info@astralpharma.co.za.

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 overdosage is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category D Medicine: Health supplement 34.11 Vitamins

5.2 Pharmacokinetic properties

Vitamin B1 (Thiamine)

Thiamine is absorbed from the gastro-intestinal tract and is widely distributed to most body tissues. Amounts in excess of the body's requirements are not stored but excreted in the urine as unchanged thiamine or its metabolites.

Vitamin B2 (Riboflavin)

Riboflavin is absorbed from the gastro-intestinal tract and in the circulation is bound to plasma proteins. It is widely distributed. Little is stored and excess amounts are excreted in the urine. In the body riboflavin is converted to flavine mononucleotide (FMN) and then to flavine adenine dinucleotide (FAD).

Vitamin B6 (Pyridoxine)

Pyridoxine is absorbed from the gastro-intestinal tract and converted to the active pyridoxal phosphate which is bound to plasma proteins. It is excreted in the urine as 4-pyridoxic acid.

Vitamin B12 (Cyanocobalamin)

Cyanocobalamin is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. A study with labelled Vitamin B12 showed it was quickly taken up by the intestinal mucosa and held there for 2 - 3 hours. Peak concentrations in the blood and tissues did not occur until 8 - 12 hours after dosage with maximum concentrations in the liver within 24 hours. Cobalamins are stored in the liver, excreted in the bile and undergo enterohepatic recycling. Part of a dose is excreted in the urine, most of it in the first eight hours.

5.3 Preclinical safety data

Not known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Stearate

Starch

6.2 Incompatibilities

Unknown

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store in a cool, dry place at or below 25 °C.

Protect from light and moisture.

Keep the container firmly closed.

6.5 Nature and contents of the container

30 Veggie capsules in an amber plastic bottle with a tamper evident seal.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Astral Pharma (Pty) Ltd

49 Riboville Road

Randjiesfontein

Midrand

1683

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 2024