

Professional information for HIGH-B

COMPLEMENTARY 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

HIGH-B® capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Thiamine HCl	25 mg
providing thiamine (vitamin B ₁)	20 mg
Pyridoxine HCl	25 mg
providing pyridoxine (vitamin B ₆)	21 mg
Calcium (D) pantothenate	20 mg
providing d-pantothenic acid (vitamin B ₅)	18 mg
Riboflavin (vitamin B ₂)	20 mg
Cyanocobalamin (vitamin B ₁₂)	25 µg

Sugar free.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsules.

Size 0 yellow capsules filled with a bright orange-yellow powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

HIGH-B is a vitamin B supplement containing vitamins B₁, B₂, B₅, B₆ and B₁₂. HIGH-B helps to metabolise carbohydrates, fats and proteins, contributes to normal growth, normal red blood cell formulation, tissue formation and is a factor in the maintenance of good health.

4.2 Posology and method of administration

Adults:

- Take 1 capsule daily.
- Do not exceed a daily intake of 4 capsules.

Children:

Not suitable for children under the age of 6 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

Paediatric population

HIGH-B is not suitable for children under the age of 6 years as the dosage form is not suitable for this age group.

4.5 Interaction with other medicines and other forms of interaction

Antibiotic medicines:

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

Diuretic medicines:

High doses of diuretics can increase excretion of HIGH-B and increase the risk of deficiency.

Caution is advised.

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

HIGH-B 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 HIGH-B are known.

4.8 Undesirable effects

HIGH-B 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: nausea, vomiting, abdominal pain, heartburn.

Renal and urinary disorders:

Frequency unknown: urine discolouration.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of HIGH-B is important. It allows continued monitoring of the benefit/risk balance of HIGH-B. 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 34.11 Vitamins.

HIGH-B is a vitamin B supplement containing vitamins B₁, B₂, B₅, B₆ and B₁₂ which helps to metabolise carbohydrates, fats and proteins, contributes to normal growth, normal red blood cell formulation, tissue formation and is a factor in the maintenance of good health.

5.2 Pharmacokinetic properties

Vitamin B₁ is a water-soluble B-vitamin and is absorbed by the proximal part of the small intestines. It occurs in the body as the metabolically active form thiamine diphosphate and is excreted in the urine.

Vitamin B₂ is readily absorbed from the gastrointestinal tract and is widely distributed in the body. It is excreted in the urine

Vitamin B₅ is an essential B vitamin. It is absorbed from the small intestines and widely distributed through the body. About 70 % is excreted unchanged in the urine, and 30 % in the faeces.

Vitamin B₆ is passively absorbed from the upper gastrointestinal tract, converted in the liver to the coenzyme pyridoxal phosphate and excreted in the urine.

Vitamin B₁₂ is an essential water-soluble vitamin. It is absorbed in the terminal ileum and is mainly stored in the liver. Orally, vitamin B₁₂ as cyanocobalamin and cyanocobalamin-SNAC has a half-life of about 25 – 30 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Di-calcium phosphate dihydrate

Gelatine capsules

Magnesium stearate.

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 capsules, 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 October 2022.