

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

HIGH B[®] capsules Vitamin B₁ / Vitamin B₂ / Vitamin B₅ / Vitamin B₆ / Vitamin B₁₂

Sugar free.

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share HIGH B with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

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

1. What HIGH B is and what it is used for

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. HIGH-B also assists where a deficiency of Vitamin B exists, eg during antibiotic treatment, to boost the immune system, oral contraception, stress, peripheral neuralgia or intercostal neuralgia.

2. What you need to know before you take HIGH B

Do not take HIGH B:

- If you are hypersensitive (allergic) to any of the ingredients of HIGH B (listed in section 6).

Warnings and precautions

Do not give HIGH B to children younger than 6 years.

Other medicines and HIGH B

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently taking:

- Antibiotics (used to treat a bacterial infection). Take antibiotics at least 2 hours before, or 4 to 6 hours after taking HIGH B.
- Diuretics / water tablets (used to treat swelling).

Pregnancy, breastfeeding and fertility

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 health care provider for advice before taking HIGH B. Safety in pregnancy and lactation has not been established.

Driving and using machines

HIGH B is unlikely to affect your ability to drive a vehicle and use machines. Do not drive or operate machinery until you know how HIGH B affects you.

3. How to take HIGH B

Always take HIGH B exactly as described in this leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure.

Adults:

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

If you take more HIGH B than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

4. Possible side effects

HIGH B can have side effects.

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

If any of the following happens, stop taking HIGH B and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to HIGH B. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequency unknown:

- Loss of appetite.
- Headache.
- Nausea (feeling sick), vomiting (being sick), stomach pain, heartburn.
- Urine discolouration.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the 6.04 Adverse Drug Reactions Reporting Form, found online under SAHPRA's publications:

<http://www.sahpra.org.za/Publications/Index/8>

By reporting side effects, you can help provide more information on the safety of HIGH B.

5. How to store HIGH B

- Store at or below 25 °C.
- Protect from light and moisture.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Contents of the pack and other information

What HIGH B contains

Each capsule contains:

Vitamin B1 (Thiamine HCl 20 mg)	25 mg
Vitamin B2 (Riboflavin 20 mg)	20 mg
Vitamin B5 (Calcium Pantothenate 18 mg)	20 mg
Vitamin B6 ((Pyridoxine HCl 21 mg)	25 mg
Vitamin B12 (Cyanocobalamine 25 µg)	25 µg

Sugar Free

The other ingredients are di-calcium phosphate dihydrate, gelatine capsules and magnesium stearate.

What HIGH B looks like and contents of the pack

Size 0 yellow capsules filled with an orange-yellow powder.

A white container containing 30 or 60 capsules, packed inside a carton.

Holder of Certificate of Registration:

Crux Pharmaceuticals
630 Jacqueline Dr
Garsfontein
Pretoria
0042
Tel: 082 805 1191

Marketed by:

Cedarpharm (Pty)Ltd
3798 Jan Frederick Avenue
Randpark Ridge
2169
www.cedarpharm.co.za

This leaflet was last revised in

October 2023.

Registration number

Will be allocated by SAHPRA upon registration.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSSTATUS

S0

HIGH B[®] kapsules Vitamiën B₁ / Vitamiën B₂ / Vitamiën B₅ / Vitamiën B₆ / Vitamiën B₁₂

Suikervry.

KOMPLEMENTÊRE MEDISYNE: GESONDHEIDSAANVULLING

Hierdie ongeregistreerde medisyne is nie vir gehalte, veiligheid of beoogde gebruik deur SAHPRA geëvalueer nie.

Lees hierdie hele inligtingsblad aandagtig deur want dit bevat inligting wat belangrik is vir jou.

HIGH B is beskikbaar sonder 'n dokter se voorskrif, sodat jy jou gesondheid in stand kan hou. Jy moet HIGH B nogtans met sorg neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie HIGH B met enigiemand anders deel nie.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat is HIGH B en waarvoor word dit gebruik.
2. Wat jy moet weet voordat jy HIGH B neem.
3. Hoe om HIGH B te neem.
4. Moontlike nuwe-effekte.
5. Hoe om HIGH B te bêre.
6. Inhoud van die pak en ander inligting.

1. Wat is HIGH B en waarvoor word dit gebruik

HIGH-B is 'n vitamien B-aanvulling wat vitamien B₁, B₂, B₅, B₆ en B₁₂ bevat. HIGH-B help om koolhidrate, vette en proteïene te metaboliseer, wat dan bydra tot normale groei, normale rooibloedselformulering, weefselvorming en is 'n faktor in die handhawing van goeie gesondheid. HIGH-B help ook waar 'n tekort aan Vitamiën B bestaan, bv tydens antibiotika behandeling, om die immuunstelsel te versterk, orale voorbehoeding, stres, perifere neuralgie of interkostale neuralgie te versterk.

2. Wat jy moet weet voordat jy HIGH B neem

Moenie HIGH B neem nie

- Indien jy hipersensitief (allergies) is vir enige van die bestanddele van HIGH B (gelys by afdeling 6).

Waarskuwings en voorsorgmaatreëls

Moenie HIGH B aan kinders jonger as 6 jaar gee nie.

Ander medisyne en HIGH B

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Sê vir jou dokter of apteker indien jy tans die volgende gebruik:

- Antibiotika (gebruik om 'n bakteriële infeksie te behandel). Neem antibiotika minstens 2 ure voor, of 4 tot 6 ure nadat jy HIGH B geneem het.
- Diuretika / watertablette (gebruik om swelling te behandel).

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy HIGH B neem. Die veiligheid tydens swangerskap en borsvoeding is nie bepaal nie.

Bestuur en die gebruik van masjiene

Dit is onwaarskynlik dat HIGH B jou vermoë om 'n voertuig te bestuur en masjiene te gebruik sal belemmer. Moenie 'n voertuig bestuur of masjinerie hanteer totdat jy weet hoe HIGH B jou affekteer nie.

3. Hoe om HIGH B te neem

Gebruik HIGH B altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou apteker vir jou gesê het. Vra gerus jou apteker indien jy onseker is.

Volwassenes:

- Neem 1 kapsule daagliks.
- Moenie 'n daaglikse inname van 4 kapsules oorskry nie.

Wat om te doen indien jy meer HIGH B geneem het as wat jy moet

In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

4. Moontlike nuwe-effekte

HIGH B kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir HIGH B gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl HIGH B geneem word, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om HIGH B te neem en sê dadelik vir jou dokter, of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk en asemhaling.
- Uitslag of gejeuk.
- Floute.

Hierdie is baie ernstige nuwe-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op HIGH B gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Neuwe-effekte wat met onbekende frekwensie voorkom:

- Verlies aan eetlus.
- Hoofpyn.
- Naarheid, braking, maagpyn, sooi-brand.
- Verkleuring van uriene.

Indien jy enige nuwe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

Aanmelding van nuwe-effekte

Indien enige nuwe-effekte ondervind word, bespreek dit met jou dokter of apteker. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die vorm om ongunstige geneesmiddelreaksies te rapporteer, wat aanlyn by SAHPRA se publikasies beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>

Deur nuwe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van HIGH B te verskaf.

5. Hoe om HIGH B te bêre

- Bêre by of onder 25 °C.
- Beskerm teen lig en vog.
- Bêre alle medisyne buite bereik van kinders.
- Moenie gebruik na die vervaldatum wat op die verpakking gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat HIGH B bevat

Elke kapsule bevat:

Vitamin B1 (Thiamine HCl 20 mg)	25 mg
Vitamin B2 (Riboflavin 20 mg)	20 mg
Vitamin B5 (Calcium Pantothenate 18 mg)	20 mg
Vitamin B6 ((Pyridoxine HCl 21 mg)	25 mg
Vitamin B12 (Cyanocobalamine 25 µg)	25 µg

Suikervry

Die ander bestanddele is di-kalsiumfosfaat dihidraat, gelatienkapsules en magnesiumstearaat.

Hoe HIGH B lyk en inhoud van die verpakking

Grootte 0 geel kapsules gevul met 'n oranje-geel poeier.

'n Wit houër met 30 of 60 kapsules, verpak in 'n karton.

Houer van die Registrasie Sertifikaat:

Crux Pharmaceuticals
Jacquelinerylaan 630
Garsfontein
Pretoria
0042
Tel: 082 805 1191

Bemerk deur:

Cedarpharm (Edms.) Bpk
Jan Fredericklaan 3798
Randparkrif
2169
www.cedarpharm.co.za

Hierdie inligtingsblad is laas hersien in

Oktober 2023.

Registrasienuommer

Vir toekenning deur SAHPRA met registrasie.