

PROFESSIONAL INFORMATION

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

BIOGEN VIRAL SUPPORT (Film-coated tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:		*%NRV
L-Lysine Hydrochloride (providing 500,00 mg Lysine)	625,00 mg	
Vitamin C (as Ascorbic acid)	50,00 mg	50 %
Vitamin B ₃ (as Nicotinamide)	10,00 mg	63 %
Vitamin B ₆ (as Pyridoxine)	10,00 mg	588 %
Zinc oxide (providing 10,00 mg elemental Zinc)	12,50 mg	91 %
Cholecalciferol (Vitamin D ₃)	12,50 µg (500 IU)	83 %
Selenium (as 0,2 % Selenium rice flour chelate)	30,00 µg	55 %
Magnafolate™ (L-5-Methyltetrahydrofolate Calcium)	200,00 µg	50 %
Vitamin B ₁₂ (as Methylcobalamin)	25,00 µg	1 042 %

*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010).

Sugar free

The **MAGNAFOLATE™** is a registered trademark of Lianyungang Jinkang Pharmaceutical Technology Co., Ltd.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

WHITE OVAL FILM-COATED TALBET.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BIOGEN VIRAL SUPPORT supports normal function of the immune and may prevent recurrent cold sores by supporting oral and immune health.

4.2 Posology and method of administration

Posology

Adults (18 years and older):

Take 2 (two) tablets daily with meals, or as recommended by your healthcare provider.

Do not exceed the recommended dose.

Paediatric population

The safety and efficacy of BIOGEN VIRAL SUPPORT has not been established in children under the age of 18.

Method of administration

For oral use.

Swallow the film-coated tablets whole and do not chew or crush.

To be taken with or after food.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN VIRAL SUPPORT. If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.

Please take note of the following:

- Patients with any medical conditions or who are taking any other medications should be advised to consult with their relevant healthcare provider prior to using BIOGEN VIRAL SUPPORT.
- Consult a healthcare provider prior to use if you are pregnant or breastfeeding.
- Not suitable for children below the age of 18 years unless under the direct supervision of a healthcare provider.

Paediatric population

Not suitable for children below the age of 18 years unless under the direct supervision of a healthcare provider.

4.5 Interactions with other medicines and other forms of interactions

No interaction studies have been conducted.

4.6 Fertility, pregnancy, and lactation

Safety in fertility, pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

BIOGEN VIRAL SUPPORT is not likely to cause drowsiness. Patients should take caution before performing activities requiring their attention, until they are reasonably certain that BIOGEN VIRAL SUPPORT does not adversely affect their performance.

4.8 Undesirable effects

BIOGEN VIRAL SUPPORT is generally well tolerated but may cause gastrointestinal discomfort in some patients.

Gastrointestinal disorders: *Frequency unknown:* nausea, vomiting, abdominal pain, stomach upset, diarrhoea, and constipation.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

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 overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Class and category: D 34.12 Multiple substance formulation.

BIOGEN VIRAL SUPPORT is a complementary medicine that supports normal function of the immune system and may prevent recurrent cold sores by supporting oral health.

Folate is involved in the synthesis of purines and pyrimidines, which are constituents of DNA, as well as the synthesis of amino acids glycine and methionine. Deficiency leads to impaired cell division.

L-Lysine is an essential amino acid, and is important for proper growth. Helps to reduce the recurrence of herpes simplex virus (HSV) infection (e.g. cold sores). Lysine appears to help the body absorb calcium, and it plays an important role in the formation of collagen.

Vitamin B₃ (niacin) functions as a component of two coenzymes, nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide diphosphate (NADP). These coenzymes participate in many metabolic processes including glycolysis, tissue respiration, lipid, amino acid, and purine metabolism.

Vitamin B₆ is converted to pyridoxal phosphate and pyridoxamine phosphate in erythrocytes. It is a cofactor for more than 100 reactions involved in the metabolism of carbohydrates, lipids, and protein. Pyridoxal phosphate is also involved in the synthesis of neurotransmitters and metabolism of other vitamins (e.g., conversion of tryptophan to niacin (vitamin B₃)).

Vitamin B₁₂ is involved in the recycling of coenzymes responsible for folate metabolism. Also involved in the degradation of Valine, an amino acid constituent of most protein.

Vitamin C acts as an antioxidant (reacting directly with aqueous free radicals), which is important in the protection of cellular function and to enhance the intestinal absorption of non-haem iron.

Vitamin D is essential for promoting the absorption and utilisation of calcium and phosphorus and normal calcification of the skeleton. It maintains neuromuscular function and various other cellular processes, including the immune system and insulin production.

Selenium functions as an integral part of the enzyme glutathione peroxidase and other selenoproteins. Glutathione peroxidase prevents the generation of oxygen free radicals that cause the destruction of polyunsaturated fatty acids in cell membranes.

Zinc plays an important role in the metabolism of proteins, carbohydrates, lipids, and nucleic acids. It is a cofactor in a range of biochemical processes, including the synthesis of DNA, RNA, and protein.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on BIOGEN VIRAL SUPPORT.

The vitamins and minerals in BIOGEN VIRAL SUPPORT are well absorbed from the gastrointestinal tract and are widely distributed to all tissues in the body.

5.3 Preclinical safety data

No pre-clinical safety data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core: Calcium phosphate, Microcrystalline cellulose, Polyvinylpyrrolidone, Magnesium stearate, and Silicon dioxide.

White film-coating: Polyethylene Glycol Graft Polymer, Talc Pharma, and Titanium Dioxide E-171.

6.2 Incompatibilities

In the absence of compatibility studies, this medicine must not be mixed with other medicines.

6.3 Shelf Life

24 Months / 2 Years.

6.4 Special precautions for storage

Protect from light and store in airtight container at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of the container

6 PVC / aluminum blister strips containing 10 coated tablets each, packed into an outer carton.

Pack size: 60 Tablets.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen.

23 Stag Road,

Glen Austin,

South Africa.

Tel: 0860 347 243.

Email: info@biogen.co.za

Website: www.biogen.co.za

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

JOB: BPS_Biogen Viral Support_60's		SIZE: 200mm x 267mm	
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>			
COLOURS:		FINISHING:	
<input type="checkbox"/> K		<input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Doming <input type="checkbox"/> Embossing	
PLEASE CHECK CAREFULLY Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.			