

# NEUROXCEL® 30 and 60 Vegetarian Capsules

## PROFESSIONAL INFORMATION

Complementary Medicine – Health Supplement

### SCHEDULING STATUS

To be assigned

### 1. NAME OF THE MEDICINE

NEUROXCEL® Hard Shell Vegetarian Capsules

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each White Capsule contains:

Vitamin B1 (Active) derived from Thiamine Pyrophosphate 25 mg	25	mg
Vitamin B6 (Active) derived from Pyridoxal-5-Phosphate Monohydrate 54 mg	50	mg
Vitamin B12 (Active) derived from Methylcobalamin 50 µg	50	µg
Vitamin D3 derived from Cholecalciferol 10 mg	1 000	IU
Folate (Active) derived from (6S)-5-Methyltetrahydrofolate 452 µg	400	µg

Hard Capsule Shell of Vegetarian Origin.

Suitable for use by Vegetarians.

Sucrose, Lactose, Gluten and Tartrazine Free.

For full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Size 0 Hard Shell Vegetarian Capsules.

Each Vegecap has a White body and White cap filled with an Off-White coloured powder.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

NEUROXCEL® is a health supplement intended to support healthy brain and nervous system functioning by contributing to:

- Tissue formation;
- Normal red blood cell formation;
- Helping the body metabolise proteins.

NEUROXCEL® may also be of benefit for immunosuppressed patients as well as for patients presenting with complications resulting from Vitamin B deficiencies.

#### 4.2 Posology and method of administration

For oral use.

Take one White Hard Shell Vegetarian Capsule daily in the Morning with Breakfast, as prescribed by your healthcare professional.

Take 2 hours before or after taking other medications or natural health products.

#### 4.3 Contraindications

Do not use if you have a hypersensitivity to any of the ingredients, including excipients listed in section 6.1.

NEUROXCEL® should not be used by persons suffering from:

- conditions associated with hypercalcaemia and hypercalciuria, and in renal impairment (chronic);
- renal osteodystrophy with hyperphosphataemia (risk of metastatic calcification).

#### 4.4 Special warnings and precautions for use

High dose Vitamin D may increase the risk of hypercalcaemia.

Not suitable for children below the age of 14 years (due to the Folate content) unless under the direct supervision of a qualified healthcare professional.

#### 4.5 Interactions with other medicines

*Alcohol:* excessive intake increases the turnover of Pyridoxine.

*Calcitonin:* effect of calcitonin may be antagonised by Vitamin D.

*Digoxin:* caution because hypercalcaemia caused by Vitamin D may potentiate effects of digoxin, resulting in cardiac arrhythmias.

*Thiazide diuretics:* Vitamin D may increase risk of hypercalcaemia and may increase excretion of Magnesium.

*Vitamin D analogues (alfacalcidol, calcitriol, dihydrotachysterol):* increased risk of toxicity with Vitamin D supplements.

#### 4.6 Fertility, Pregnancy and Breastfeeding

Always check with your doctor or pharmacist before taking any medicines if you are planning to have a baby, pregnant or breastfeeding.

The ingredients as contained in NEUROXCEL® are commonly used in pregnancy products.

#### 4.7 Effects on ability to drive and use of machines

None.

#### 4.8 Undesirable effects

Organ System	Less Frequent	Frequent
Gastrointestinal discomfort	Nausea, diarrhoea, constipation, indigestion, bloating and flatulence.	
Urinary		Bright yellow urine

#### Reporting of suspected adverse reactions:

If you experience any adverse reactions not mentioned in this leaflet, report it to AnaStellar Brands (Pty) Ltd via [pharmacist@anastellar.co.za](mailto:pharmacist@anastellar.co.za), (011) 792 4601 or <https://anastellar.co.za>.

#### 4.9 Overdose

Treatment of overdose should be symptomatic and supportive.

### 5. PHARMACOLOGICAL PROPERTIES

#### 5.1 Pharmacodynamic properties

**Vitamin B1:** Thiamine functions as a coenzyme in the oxidative decarboxylation of alpha ketoacids (involved in energy production) and in the transketolase reaction of the pentose phosphate pathway (involved in carbohydrate metabolism). Thiamine is also important in nerve transmission (independently of coenzyme function).

**Vitamin B6:** 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 proteins. 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:** Vitamin B12 is involved in the recycling of coenzymes responsible for Folate metabolism and in the degradation of valine, an Amino Acid constituent of most proteins. It is also required for nerve myelination, cell replication, haematopoiesis, and nucleoprotein synthesis.

**Vitamin D3:** Vitamin D is essential for promoting the absorption and utilisation of Calcium and Phosphorus and normal calcification of the skeleton. Along with parathyroid hormone (PTH) and calcitonin, it regulates serum Calcium concentration by altering serum Calcium and Phosphate blood levels as needed, and mobilising Calcium from bone. It maintains neuromuscular function and various other cellular processes, including the immune system and insulin production.

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

### 6. PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Magnesium Stearate  
Maize Starch  
Microcrystalline Cellulose

#### 6.2 Incompatibilities

None.

#### 6.3 Shelf life

2 years.

#### 6.4 Special precautions for storage

Store at or below 25 °C.  
Protect from light and moisture.  
Keep the blister strips in the outer carton until required for use.  
KEEP OUT OF REACH OF CHILDREN.

#### 6.5 Nature and contents of container

NEUROXCEL® is available in a pack of 30 and 60 White Hard Shell Vegetarian Capsules. 10 x Size 0 White Hard Shell Vegetarian Capsules contained in each PVC/PVDC/Aluminium blister strip.

#### Packed product:

**Pack of 30's**  
3 x PVC/PVDC/Aluminium blister strips enclosed within a cardboard carton.  
Pack size of 30 x White Hard Shell Vegetarian Capsules.  
Unit Carton with 1 x Tamper Proof Seal on each side of the lid openings.

**Pack of 60's**  
6 x PVC/PVDC/Aluminium blister strips enclosed within a cardboard carton  
Pack size of 60 x White Hard Shell Vegetarian Capsules.  
Unit Carton with 1 x Tamper Proof Seal on each side of the lid openings.

#### 6.6 Special precautions for disposal

No special requirements.

### 7. Holder of Certificate of Registration

AnaStellar Brands (Pty) Ltd.  
PO Box 639  
Fontainebleau  
2032  
South Africa  
+27 (0)11 792 4601

#### 8. Registration number

To be assigned

#### 9. Date of first authorisation

Not applicable

#### 10. Date of revision of the text

October 2024

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