

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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### 1. NAME OF THE FINISHED PRODUCT

Neurovit Film-Coated Tablet

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS	PER TABLET (MG)
Thiamine Mononitrate	97.00 mg
Pyridoxine HCl	50.00 mg
Cyanocobalamin	100.00 mcg

Kindly refer to Section 6.1 for excipient.

### 3. PHARMACEUTICAL FORM

Round, peach film-coated tablet, bevel-edged, shallow convex faces

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indication

For treatment of nutritional vitamin B1, B6 and B12 deficiencies, peripheral neuritis and in conditions requiring increased intake such as alcoholism, hepatic disease, hyperthyroidism, infection, lactation, pregnancy and malabsorption syndromes.

#### 4.2 Posology and Method of administration

Adult: Oral, 1 tablet daily; or as directed.

Children: As directed by the physician.

Note: The information given here is limited. For further information consult your doctor or pharmacist.

#### 4.3 Contraindication

Not recommended for patients with Leber's disease since optic nerve atrophy may occur.

#### 4.4 Warnings and precautions

Not applicable

#### 4.5 Drug Interactions

Neurovit Tablet may reduce the effects of levodopa.

#### 4.6 Pregnancy and lactation

Not applicable

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

Not applicable

**4.8 Main Side/ Adverse Effects**  
Diarrhoea and itching may occur occasionally.

**4.9 Overdose**  
Neurovit Tablet is usually well tolerated.

## **5. PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**  
The B vitamins are essential for growth, cell replication, tissue respiration, haematopoiesis, nucleoprotein and myelin synthesis, as well as for various metabolic functions, including metabolism of carbohydrates, proteins and lipids.

**5.2 Pharmacokinetic properties**  
They are readily absorbed orally except in malabsorption syndromes, metabolised in the liver and excreted mainly via the kidneys.

**5.3 Preclinical Safety Data**  
Not applicable

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Lactose monohydrate  
Cornstarch  
Microcrystalline Cellulose pH 101  
Sodium starch glycolate  
Polyvinylpyrrolidone K25  
Magnesium stearate  
Copovidone  
Iron oxide yellow  
Sunset yellow lake  
Talc  
Titanium dioxide  
Hydroxypropyl methylcellulose E-5  
Hydroxypropyl methylcellulose E-15  
Propylene glycol  
Isopropyl alcohol

**6.1 Incompatibilities**  
Not applicable

**6.2 Shelf life**  
2 years from date of manufacture

**6.3 Special precaution for storage**

Store below 25°C. Protect from light and moisture.

**6.4 Nature and contents of container**

Immediate Container / Packaging

Blister Pack

Type:

Push-through blister pack; the package consists of a transparent thermoformable plastic material and a heat-sealable lacquered backing material.

Material:

Thermoformable plastic material : Polyvinyl Chloride (PVC)

Backing Material : Aluminium Foil

**6.5 Instructions for use and handling <and disposal>**

Not Applicable

**7. MARKETING AUTHORISATION HOLDER**

Name : HOVID Bhd.  
Address : 121, Jalan Tunku Abdul Rahman,  
(Jalan Kuala Kangsar)  
30010 Ipoh, Perak, Malaysia

Manufacturer Name :

Name : HOVID Bhd.  
Address : Lot 56442, 7 ½ Miles,  
Jalan Ipoh / Chemor,  
31200 Chemor,  
Perak., Malaysia.

**8. NUMBER (S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS**

HOV/MAL/025

**9. DATE OF FIRST AUTHORISATION**

2017

**10. DATE OF REVISION OF THE TEXT**

August 2020