

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

VITAMIN B COMPOUND STRONG FILM-COATED TABLETS

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each tablet contains 20mg Nicotinamide, 2mg Pyridoxine Hydrochloride, 2mg Riboflavine, 4.85mg Thiamine Mononitrate .

Also contains lactose.

For a full list of excipients, see section 6.1

### **3 PHARMACEUTICAL FORM**

Film-coated tablet (tablet).

Brown, circular, biconvex film-coated tablets with the identifying letters “VB” embossed on one side.

### **4. CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

1) For the treatment of clinical and sub-clinical vitamin B deficiency states (manifestations of which include glossitis, stomatitis, cheilosis, the heart manifestations of beriberi, the skin manifestations of pellagra, corneal vascularisation and polyneuritis).

#### **4.2 Posology and method of administration**

*Adults (including elderly) and children over 3 years:* One to two tablets three times daily.

*Children under 3 years:* Not recommended.

For oral administration.

### **4.3 Contraindications**

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

### **4.4 Special warnings and precautions for use**

#### Excipients

##### *Lactose:*

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

### **4.5 Interactions with other medicinal products and other forms of interaction**

Pyridoxine may increase the peripheral metabolism of levodopa, reducing therapeutic efficacy of the latter drug. Therefore, patients with Parkinson's disease who are receiving treatment with plain levodopa should not take vitamin B<sub>6</sub> in doses which greatly exceed the daily requirement. This does not apply when levodopa is combined with a peripheral decarboxylase inhibitor.

### **4.6 Fertility, pregnancy and lactation**

The usual precautions should be observed when administering drugs during pregnancy, especially in the first trimester.

In high doses, pyridoxine may interfere with prolactin release and should only be used with caution in nursing mothers.

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

None known.

### **4.8 Undesirable effects**

Toxic effects are unlikely since any excess vitamin B is excreted.

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal

product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

#### **4.9 Overdose**

Excess vitamin B is readily excreted, therefore no serious problems are anticipated for the administration of vitamin B in this form.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

ATC Name: Vitamin B-complex, plain  
ATC Code: A11EA

Nicotinamide is a vitamin  
Pyridoxine hydrochloride is a vitamin (B<sub>6</sub>)  
Riboflavine is a vitamin (B<sub>2</sub>)  
Thiamine mononitrate is a vitamin (B<sub>1</sub>)

The vitamin B-complex comprises a group of water-soluble factors more or less closely associated in their natural occurrence. It is known that nearly every vitamin of the B-complex forms part of a co-enzyme essential for the metabolism of protein, carbohydrate or fatty acid.

### **5.2 Pharmacokinetic properties**

Nicotinamide is readily absorbed from the GI tract following oral administration and is widely distributed in the body tissues. Small amounts of nicotinamide are excreted unchanged in urine following therapeutic doses, however, the amount excreted unchanged is increased with larger doses.

Pyridoxine is absorbed from the GI tract and is converted to the active form pyridoxal phosphate. It is excreted in the urine as 4-pyridoxic acid.

Riboflavine is absorbed from the GI tract and in the circulation is bound to plasma proteins. Although widely distributed, little is stored in the body, and amounts in excess of requirements are excreted in the urine.

Thiamine is absorbed from the GI tract and is widely distributed to most body tissues. It is not stored to any appreciable extent in the body and amounts in excess of requirements are excreted in the urine as unchanged thiamine or metabolites.

### **5.3 Preclinical safety data**

Not applicable.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Tablet core contains:

Lactose monohydrate  
Magnesium stearate  
Maize starch  
Pregelatinised maize starch  
Stearic acid

Film-coat contains:

Hypromellose  
Hydroxypropyl Cellulose  
Medium Chain Triglycerides  
Macrogol 3350  
Titanium Dioxide (E171)  
Iron oxide Red (E172)  
Iron oxide Black (E172)

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

*Shelf-life*

Two years from the date of manufacture.

*Shelf-life after dilution/reconstitution*

Not applicable.

*Shelf-life after first opening*  
Not applicable.

#### **6.4 Special precautions for storage**

Store below 25°C in a dry place.

#### **6.5 Nature and contents of container**

The product containers are rigid injection moulded polypropylene or injection blow-moulded polyethylene tablet containers with polyfoam wad or polyethylene ullage filler and snap-on polyethylene lids; in case any supply difficulties should arise the alternative is amber glass bottles with screw caps and polyfoam wad or cotton wool.

The product may also be supplied in blister packs in cartons:

- a) Carton: Printed carton manufactured from white folding box board.
- b) Blister pack: (i) 250µm white rigid PVC. (ii) Surface printed 20µm hard temper aluminium foil.

Pack sizes: 28, 30, 56, 60, 84, 90, 100, 112, 120, 168, 180, 250, 500, 1000.

Product may also be supplied in bulk packs, for reassembly purposes only, in polybags contained in tins, skillets or polybuckets filled with suitable cushioning material. Bulk packs are included for *temporary* storage of the finished product before final packaging into the proposed marketing containers.

Maximum size of bulk packs: 50,000.

Not all pack sizes may be marketed.

#### **6.6 Instructions for use/handling**

Not applicable.

## **7 MARKETING AUTHORISATION HOLDER**

Accord-UK Ltd

(Trading style: Accord)

Whiddon Valley

Barnstaple

Devon

EX32 8NS

**8. MARKETING AUTHORISATION NUMBER**

PL 0142/5538 R

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Granted: 19.9.86

(Product Licence of Right: 31.5.73)

(Renewed: 23.12.91, 26.4.99)

**10 DATE OF REVISION OF THE TEXT**

23/05/2023