Vitamin B Compound Strong Tablets

Summary of Product Characteristics Updated 14-May-2020 | Accord-UK Ltd

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 Interaction 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_6 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 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 Code: A11EA

ATC Name: Vitamin B-complex, plain

Nicotinamide is a vitamin

Pyridoxine hydrochloride is a vitamin (B_6)

Riboflavine is a vitamin (B_2)

Thiamine mononitrate is a vitamin (B_1)

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 with 5-7g/M^2 PVC and PVdC compatible heat seal lacquer on the reverse side.

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 Special precautions for disposal and other handling

Not applicable.

Administrative Data

7. Marketing authorisation holder

Accord-UK Ltd

(Trading style: Accord)

Whiddon Valley

Barnstaple

Devon

EX32 8NS

8. Marketing authorisation number(s)

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

06/05/2020

Company Contact Details

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