SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Vitamin B Tablets Compound BPC

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Thiamine Hydrochloride 1.00 mg, Riboflavin 1.00 mg and
Nicotinamide 15.00 mg.

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Tablets

4.1 Therapeutic indications

For the prophylaxis of Vitamin B deficiencies; as a nutritional supplement in the elderly; and as an aid to convalescence after illness or surgery.

4.2 Posology and method of administration

Dosage

Adults. Elderly and Children over 12 years

One or two tablets daily.

Children under 12 years

Not recommended.

Route of administration: Oral

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

These tablets are not suitable for the treatment of symptomatic Vitamin B complex deficiencies.
This product contains 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

Not known

4.6 Fertility, pregnancy and lactation

Widespread use over the years has not shown any problems when used during pregnancy and breastfeeding.

4.7 Effects on ability to drive and use machines

Vitamin B Compound Tablets BPC has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

None known.

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 at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

If large amounts are ingested accidentally, treat symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Thiamine combines with adenosine triphosphate (ATP) to form a coenzyme, thiamine pyrophosphate (thiamine diphosphate cocarboxylase) which is necessary for carbohydrate metabolism.

Riboflavin is converted to two coenzymes, flavine mononucleotide (FMN) and flavine adenine dinucleotide (FAD) which are necessary for normal tissue respiration. Riboflavin is also required for the activation of pyridoxine and may be involved in maintaining erythrocyte integrity.

Nicotinamide is a component of two coenzymes, nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP) which are necessary for lipid metabolism, tissue respiration and glycogenolysis.

5.2 Pharmacokinetic properties

Thiamine hydrochloride, riboflavin and nicotinamide are well absorbed from the gastrointestinal tract mainly the duodenum and jejunum.

Absorption of large doses are limited. Alcohol inhibits the absorption of these vitamins.

The vitamins are widely distributed to most body tissues and appear in breast milk. Excess beyond daily requirements are excreted via urine as unchanged or as metabolites. Biotransformation of vitamins occur in the liver.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Maize Starch
Pregelatinised Starch
Magnesium Stearate

6.2 Incompatibilities

Incompatible with alkalis and salts of heavy metals.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Keep out of the reach and sight of children. Store in container provided and protect from heat, light and moisture.

6.5 Nature and contents of container

The product is packed in:

a) Opaque plastic containers fitted with plastic snap-on closures in pack sizes of 28, 30, 42, 50, 56, 60, 84, 90, 100, 112, 250, 500 and 1,000 tablets.
b) Opaque plastic containers composed of either high density polypropylene or high density polyethylene with a tamper-evident or child-resistant tamper-evident closure composed of high density polyethylene in all pack sizes (28, 30, 42, 50, 56, 60, 84, 90, 100, 112, 250, 500 and 1,000 tablets). Packing inclusion:
standard polyether foam or polyethylene or polypropylene filler.
c) Blister packs of aluminium / opaque PVC subsequently packed in printed cartons in pack sizes of 28, 30, 56, 60, 84, 90 and 112.

6.6 Special precautions for disposal

No special instructions for use/handling.

7 MARKETING AUTHORISATION HOLDER

Crescent Pharma Limited
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8 MARKETING AUTHORISATION NUMBER(S)

PL 20416/0409

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17/02/2010

10 DATE OF REVISION OF THE TEXT

29/09/2025