SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Vitamin B Compound Strong Tablets BPC.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each coated tablet contains Thiamine HCI 5 mg, Riboflavin 2 mg, Nicotinamide 20 mg and Pyridoxine HC1 2 mg

For excipients, see 6.1

3. PHARMACEUTICAL FORM

Brown, film coated convex tablets.

4.1 Therapeutic indications

Recommended clinical indication

For the treatment of mild chronic vitamin deficiency.

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

Dosage
Adults, elderly and children over 3 years: 1 - 2 tablets three times daily.

Paediatric population
Should not be used in children under 3 years.

Route of administration: Oral

4.3 Contraindications

Hypersensitivity, to thiamine hydrochloride, riboflavin, pyridoxine hydrochloride and nicotinamide.

4.4 Special warnings and precautions for use

Patients with rare hereditary problems of galactose or fructose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption or sucrase-isomaltase insufficiency 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

Pregnancy:
There is limited amount of data from the use of the product in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. The use of the product is individualized based on condition and requirements in pregnant women and can be used in pregnant women if use is necessary to correct deficiencies and if benefits overweighs risks.
Caution should be exercised when prescribing to pregnant women.

Breast-feeding:

The ingredients of Vitamin B compound tablets are excreted via human milk. No harm to suckling infant is expected if used in recommended doses. High concentrations of vitamin B_6 can inhibit the production of breast milk. However, the use should be individualized based on nutritional status of the lactating women and infant. The diet and use of any additional B vitamin supplements in both mother and infant should be reassessed so that neither excess nor lesser B vitamins available to lactating women and infant.

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

Fertility: No relevant data is available.

4.7 Effects on ability to drive and use machines

None reported

4.8 Undesirable effects

Vitamin B Compound Strong tablets are unlikely to cause any side effects, as any excess vitamin B is naturally excreted from the body.

Seek medical attention right away if any of these SEVERE side effects like severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); feeling of swelling of the entire body; numbness or tingling of the skin occur while taking Vitamin B Compound Strong).

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

Excess vitamin B is readily excreted, adverse effects are not normally expected from an acute overdose of the water-soluble vitamins contained in this preparation.

5.1 Pharmacodynamic properties

Nicotinamide is a vitamin
Pyridoxine hydrochloride is a vitamin
(B_6)
Riboflavine is a vitamin (B_2)
Thiamine Hydrochloride is a vitamin (B_1)

The ATC code of Vitamin B complex is A11EA. 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

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.

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

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use and development.

6.1 List of excipients

Lactose (E270)
Maize Starch
Pregelatinised Starch
Stearic acid
Coating components
Hydroxypropyl cellulose
Hypromellose
Talc
Titanium Dioxide (E171)
Iron oxides (E172),

6.2 Incompatibilities

None.

6.3 Shelf life

24 months for blister pack

6.4 Special precautions for storage

Do not store above 30ºC.
Store in container provided and protect from heat, light and moisture.

6.5 Nature and contents of container

Blister packs of aluminium/opaque PVC/PVDC in pack sizes of 28, 30, 56, 60, 84, 90 and 112.

Not all pack sizes may be marketed

6.6 Special precautions for disposal

No special instructions for use/handling.

7. MARKETING AUTHORISATION HOLDER

Crescent Pharma Limited
Key House, Sarum Hill,
Basingstoke, RG21 8SR,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 20416/0410

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17/02/2010

10 DATE OF REVISION OF THE TEXT

11/11/2025