

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Vitamin B Compound Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains
Nicotinamide 15.0 mg
Thiamine Hydrochloride 1.0 mg
Riboflavin 1.0 mg.

Excipient with known effect:

Lactose 122 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet.

Plain yellow, uncoated biconvex tablet

4 CLINICAL PARTICULARS

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

Posology

Adults, the elderly and children over 12 years: One to three tablets daily.

Not recommended for children under 12 years of age.

Method of administration

For oral use.

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

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

This medicine 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

None 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 have 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

A11E A – Vitamin B-Complex, Plain

Thiamine is phosphorylated in the body and acts as a co-enzyme in carbohydrate metabolism.

Riboflavin is also phosphorylated to give co-enzymes in the respiratory chain and oxidative phosphorylation.

Nicotinamide is also active in the respiratory chain.

Symptomatic nutritional vitamin B deficiency commonly involves these three vitamins.

5.2 Pharmacokinetic properties

The three vitamins are all well absorbed from the gastro-intestinal tract and are widely distributed in the body tissues. Thiamine and Riboflavin are not stored in the body and are excreted mainly in the urine. Nicotinamide is also widely distributed and has a short half-life. It is excreted mainly as metabolites.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Potato Starch
Stearic Acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 months in plastic containers.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container. Keep the container tightly closed.

6.5 Nature and contents of container

PP or HDPE tablet containers.

Pack sizes 28, 100 & 1000 tablets. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Crescent Pharma Limited
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8 MARKETING AUTHORISATION NUMBER(S)

PL 20416/0281

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14/01/2025

10 DATE OF REVISION OF THE TEXT

21/05/2026