

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

BEVITCO/Aneurine Co. Forte Tablets
Vitamin B Compound strong Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

Thiamine Hydrochloride	5.00 mg
Riboflavin	2.00 mg
Nicotinamide	20.00 mg
Pyridoxine Hydrochloride	2.00 mg

Excipient(s) with known effect

Each tablet also contains glucose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Dark chocolate film-coated, engraved tablet with approximately 7.2 mm in diameter

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of clinical and subclinical vitamin B deficiency states as manifested by glossitis, stomatitis, cheilosis, the heart manifestations of beriberi, the skin manifestations of pellagra, corneal vascularisation and polyneuritis.

4.2 Posology and method of administration

Posology

Adults and children over 3 years: 1–2 tablets three times daily

Elderly: Same dose as for adults

Children under 3 years: Not recommended

Method 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

Patients with rare hereditary problems of galactose intolerance, the Lapp 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 B₆ 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.

Severely thiamine (Vitamin B₁) deficient mothers should avoid breast-feeding as toxic methyl-glyoxal is present in milk.

4.7 Effects on ability to drive and use machines

None stated

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 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 (water soluble), therefore no serious problems are anticipated for vitamin B in this form.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

All the members of the B-Complex group are water soluble.

Riboflavin is an orange-yellow crystalline powder with a slight odour and bitter taste; and is incompatible with alkalis and salts of heavy metals. The other members are all white crystalline powders.

Thiamine has a meat-like odour and bitter taste and is incompatible with oxidising and reducing substances.

Nicotinamide is incompatible with alkalis and mineral acids.

5.2 Pharmacokinetic properties

Thiamine: Rapidly absorbed from GI tract. Widely distributed in most body tissues. Amounts in excess of requirements excreted unchanged or as metabolites.

Riboflavin: Absorbed from GI tract. Bound to plasma proteins. Excess of requirements excreted in urine. Converted in body to flavine mononucleotide and then to flavine adenin di-nucleotide.

Pyridoxine: Converted to and excreted as 4-pyridoxic acid.

Nicotinamide: Rapidly absorbed from the GI tract. Widely distributed in body tissues; has a short half-life.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Talc
Magnesium Stearate
Stearic Acid
Glucose Monohydrate
Colloidal Anhydrous Silica

Coating

Ethylcellulose
Hypromellose 5/6 cps
Diethyl Phthalate
Hydroxypropyl Cellulose
Titanium Dioxide
Iron Oxide Yellow
Iron Oxide Red
Iron Oxide Black
Ethanol Anhydrous

6.2 Incompatibilities

None stated

6.3 Shelf life

None stated

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

High density polyethylene containers with polythene lids and/or polypropylene containers with polypropylene or polythene lids and polyurethane/polythene inserts
Pack sizes: 100 and 500 tablets

Blister packs of PVC/Aluminium foil
Pack sizes: 28 tablets

6.6 Special precautions for disposal

No special requirements for disposal

7 MARKETING AUTHORISATION HOLDER

Hualan Pharmaceuticals Limited
16/17 College Green, Dublin
D02 V078
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

PL 52104/0015

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

10 DATE OF REVISION OF THE TEXT

01/10/2021