SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Product Name: Neurobest® F. C. Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Thiamine Mononitrate .....100 mg

Pyridoxine Hydrochloride .....200 mg

Cyanaocobalamin .....200 mcg.

For full list excipients Please refer to 6.1.

3. PHARMACEUTICAL FORM

Tablet (Film coated).

It is smooth well formed, light pink colored, vanilla flavored, round biconvex film coated tablet with both sides plain.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Neurobestâ tablets are indicated for chronic pains like sciatica, lumbago, trigeminal neuralgia, facial paralysis, optic neuritis as well as neuropathy & cardiac complications. Besides these, deficiency exists of these relevant vitamins.

4.2 Posology & method of administration

1-2 tablets three times a day or as directed by the physician.

4.3 Contraindications

It should not be used in patients on levodopa therapy.

4.4 Special warnings and precautions for use

Precautions: This combination (Vitamin B_1+B_6+B_{12}) should be avoided in case of hypersensitivity to Thiamine, cobalt or any other components of these ingredients.

Cyanocobalamin should not be given before a diagnosis has been fully established because of the masking symptoms of sub acute degeneration of spinal cord.

4.5 Interaction with other medicinal products and other forms of interaction

Pyridoxine (vitamin B_6) reduces therapeutic effect of levodopa therapy but if does not occur if a dopa decarboxylase inhibitor is also given. Neomycin, Chloramphenicol, aminosalisylic acid & histamine H_2 receptor antagonist may reduce vitamin B_{12} absorption.

4.6 Fertility, pregnancy and lactation

Use in Pregnancy: Neurobest[â] is safe for pregnant women.

Use in Lactating Mother: It is not known whether thiamin (vitamin B_1) is excreted in breast milk or not but may be taken cautiously during lactation. There is no known adverse effect on vitamin B_{12} therapy also.

4.7 Effects on ability to drive and use machines

Neurobest® F.C. Tablets do not affect the capability to drive a vehicle or to operate machinery.

4.8 Undesirable effects

Generally safe when a person follows the instructions on the package leaflet. In some cases, doses of B vitamins can turn the urine bright yellow. This effect is temporary and harmless. Taking too much of the product may cause side effects such as excessive urination, nausea, vomiting, diarrhoea & nerve damage.

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 pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Not available

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Dietary supplements.

ATC code: A11DB

Mechanism of action: Neurobest® is a combination of Vitamin B_1 (Thiamine), Vitamin B_6 (Pyridoxine) & Vitamin B_{12} (Cyanocobalamin).These vitamins play essential role as coenzyme in the metabolism of nervous system. Thus this combination normalizes the nerve cell metabolism.

Pharmacodynamic effects: Neurobest® supports the regeneration of nerve fibers and myelin sheath by activation of the metabolism and the natural repair mechanism. The combination of these 3 vitamins show better efficacy than that of the individual component. In addition, Vitamin B_1, B_6 & B_{12} promote body's own repair mechanism and work in pain management.

5.2 Pharmacokinetic properties

Absorption

Thiamine Mononitrate (B_1): Thiamin is absorbed from the lumen of the small intestine—mainly the jejunum—by active transport and passive diffusion mechanisms. At lower amounts, absorption from the small intestine is by an active, carrier-mediated process that is energy-dependent as well as sodiumdependent. Passive diffusion occurs with higher amounts of thiamin. Absorption of thiamin appears to be limited by a saturable rate-limiting transport mechanism. Only a small percentage of a high dose of thiamin is absorbed. Certain lipidsoluble thiamin derivatives known as allithiamins, do not appear to be subject to the rate-limiting transport mechanism. Thiamin is transported by the portal circulation to the liver and by the systemic circulation to various tissues in the body. Thiamin is metabolized to thiamin monophosphate (TP, TMP), thiamin pyrophosphate (TPP, cocarboxylase, thiamin diphosphate, TDP) and thiamin triphosphate (TTP). Thiamin is phosphorylated directly to thiamin pyrophosphate by thiamin diphosphokinase and thiamin pyrophosphate is dephosphorylated to thiamin monophosphate via thiamin diphosphatase.

Pyridoxine Hydrochloride (B_6): The phosphylated forms of vitamin B_6 undergo hydrolysis in the small intestine via alkaline phosphatase, and the

nonphosphorylated forms of the vitamin are absorbed by a nonsaturable passive diffusion process, mainly in the jejunum.

Cyanocobalamin (B_{12}): Absorption occurs almost exclusively in the terminal ileum by an active saturable process, but large amounts (>30 µg) may also be absorbed by passive diffusion (a maximum of 1.5 µg may be absorbed from oral doses of 5– 50 µg). For normal absorption, the vitamin must bind to salivary haptocorrin and then to 'intrinsic factor', a highly specific glycoprotein secreted by the parietal cells of the stomach.

Distribution:

Thiamine Mononitrate (B_1): Thiamine is transported in the plasma bound to albumin and stored in the heart, liver, muscle, kidneys and brain. Only small amounts are stored and turnover is relatively high, so continuous intake is necessary. Thiamine crosses the placenta and is distributed in breast milk. Pyridoxine Hydrochloride (B_6): Vitamin B_6 is stored in the liver, muscle and brain. Pyridoxal phosphate is transported in the plasma (bound to albumin) and in erythrocytes (in association with haemoglobin). Pyridoxal crosses placenta and is distributed into breast milk.

Cyanocobalamin (B_{12}): Vitamin $B_{12}$is stored mainly in the liver. In the blood, it is bound to specific plasma proteins (transcobalamins).

Biotransformation: N/A **Elimination:**

Thiamine Mononitrate (B_1): Thiamine is eliminated mainly in the urine (as metabolites). Excess beyond requirements is excreted as free thiamine.

Pyridoxine Hydrochloride (B_6): Primarily in the urine (mainly as metabolites), but excess amounts are excreted largely unchanged.

Cyanocobalamin (B_{12}): Vitamin B_{12} is secreted in the bile and reabsorbed via the enterohepatic circulation. Some of the B_{12} secreted in the bile is excreted in the feces.

5.3 Preclinical safety data

Not available

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients Core

Tablet:

Starch, Pregelatinized (1500)

Maize Starch

Crospovidone

Magnesium Stearate

Purified Water Coated

Tablet:

Hydroxypropyl Methylcellulose 04~ 08 cps

Titanium Dioxide

Purified Talc

Polyethylene Glycol (6000)

Red Lake Pharma Grade

Isopropyl Alcohol

Dichloromethane

Opadry OY-S-29038 (Vanilla Flavored) Pharma Grade

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store in a cool (below 30°C) and dry place, away from light and children.

6.5 Nature and contents of container Alu

– Alu blister pack.

Each strip contains 10 tablets.

Each trade pack contains 3 blister pack of 10 tablets (i.e. 3 x 10 = 30 tablets).

6.6 Special precautions for disposal and other handling

No special requirements but any unused medicine should be disposed properly. Consult your pharmacist or local waste management center for more details about how to safely discard expired or unused medicines.

7 MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

Name : **Renata Limited**

Address : **Corporate Head Office**

Plot # 1, Milk vita road, Section-VII, Mirpur,

Dhaka-1216, Bangladesh

Manufacturing Site Address

Plot # 1, Milk vita road, Section-VII, Mirpur,

Dhaka-1216, Bangladesh

8 MARKETING AUTHORISATION NUMBER

20735 (Kenya)

9 DATE OF FIRST AUTHORISATION/ DATE OF RENEWAL AUTHORISATION

24/06/2026

10 DATE OF REVISION OF THE TEXT

24/06/2026