1.6 Product information

1.6.1 Prescribing information (Summary of Product Characteristics)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

NEURO FORTE Tablets

1.1 Strength:

Each film coated tablet contains:

Vitamin B1 USP…….200 mg

Vitamin B6 USP……50 mg

Vitamin B12 USP……1000 mcg

Colour: Erythrosine

1.2 Pharmaceutical form:

Pink coloured, round film coated tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION:

2.1 Qualitative Declaration

Sr. No.	Name of Raw Materials	Specification
1	Vitamin B1	USP
2	Vitamin B6	USP
3	Vitamin B12	USP
4	Dibasic Calcium Phosphate	BP
5	Croscarmellose Sodium	USP/NF
6	Polyvinylpyrrolidone K-30	BP
7	Starch	BP
8	Lactose	BP
9	Isopropyl Alcohol	BP
10	Talc	USP/NF
11	Magnesium Stearate	BP
12	Crospovidone	USP/NF
13	Purified Water	BP
14	Tabcoat TC Pink TC540049 HIS-T021	IHS

2.2 Quantitative Declaration

Batch Size: 6,00,000

Sr. No.	Name of Raw Materials	Qty./tablet in mg	Standard batch quantity in Kg
1	Vitamin B1 USP	200.000*	33.000
2	Vitamin B6 USP	50.000*	8.250
3	Vitamin B12 USP	1000.000 mcg*	0.900
4	Dibasic Calcium Phosphate BP	18.112	10.875
5	Croscarmellose Sodium USP	10	6.000
6	Polyvinylpyrrolidone K-30 BP	1.5	0.900
7	Starch BP	5.000	3.000
8	Lactose BP	15.000	9.000
9	Isopropyl Alcohol BP	8.334	5.000
10	Talc USP	6.000	3.600
11	Magnesium Stearate BP	6.000	3.600
12	Crospovidone USP	20.000	12.000
13	Purified Water BP	Q.S.	Q.S
14	Tabcoat TC Pink TC540049 HIS-T021	16.000	9.600

*** - 10% overages added to Vitamin B1 & B6**
*** - 50% overages added to Vitamin B12**

3. PHARMACEUTICAL FORM:

Suspension

Pink coloured, round film coated tablets.

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

Neuro-Forte is indicated as an adjuvant in the treatment of neuritis pain – acute or chronic neuritis and polyneuritis.

Neuro-Forte is also indicated in the treatment of neuralgia due to toxic damage to nerve tissue, alcoholism, diabetic polyneuropathy or drug intoxication.

Neuro-Forte may also be used for the prophylaxis of vitamin B_6 deficiency during treatment with isoniazid, penicillamine, cycloserine and hydralazine.

Multivitamin preparations have been used in the treatment of rheumatic pain.

4.2 Posology and

Tablets for Oral Route of Administration.

The dosage should be adapted to each individual case. The usual recommended dose of Neuro-Forte is 1-4 tablets daily. In severe pain the treatment should be initiated with 4 tablets daily and should be continued till the pain subsides, or as directed by the physician.

4.3 Method of administration: as directed by the physician.

4.4 Contraindications:

Neuro-Forte is contraindicated in patients with hypersensitivity to vitamin B1, B6 or B12.

Owing to the vitamin B12 content of the preparation, patients with psoriasis should not receive Neuro-Forte tablets.

4.5 Special warnings and precautions for use:

Oral administration of vitamin B12 is only possible if gastrointestinal tract is functioning normally.

4.6 Pregnancy and Lactation

Neuro-Forte may be taken during pregnancy and lactation. Controlled studies in women have shown no risks to the foetus during the first trimester. There is no evidence suggesting a risk in the course of the remaining trimesters and there is little probability of possible damage to the foetus.

4.7 Interaction with other medicinal products and other forms of interaction:

The effect of levodopa is diminished by vitamin B_6

4.8 Additional information on special populations

4.9 Pediatric population

None.

4.10 Fertility, Pregnancy and lactation:

4.10.1 General principles

4.10.2 Woman of childbearing potential / Contraception in males and females.

4.10.3 Pregnancy

4.10.4 Breastfeeding

4.10.5 Fertility

Neuro-Forte may be taken during pregnancy and lactation. Controlled studies in women have shown no risks to the foetus during the first trimester. There is no evidence suggesting a risk in the course of the remaining trimesters and there is little probability of possible damage to the foetus.

4.11 Effects on ability to drive and use machines:

None stated.

4.12 Undesirable effects:

Hypersensitivity reactions are rare and are observed mainly in the skin. Erythema, desquamation of facial skin, rash and acne can be attributed to the vitamins.

4.13 Pharmacokinetic properties:

Thiamine

Vitamin B1 administered orally is assumed to have a dose-dependent dual transport mechanism, namely active absorption up to concentrations of 2 µmole and passive diffusion with concentrations over 2 µmole. According to investigations using labelled thiamine absorption is greatest in the duodenal loop and occurs to a lesser extent in the upper and middle sections of the small intestine. There is virtually no absorption in the stomach and in distal sections of the small intestine. Thiamine synthesised by the flora of the colon is not absorbed. Absorption of thiamine takes place after phosphorylation in the epithelial cells; a carrier mechanism is assumed to be involved in passage through the intestinal wall.

The fatsoluble thiamine derivatives are better absorbed than the water-soluble. Thiamine is excreted with a half-life of 1.0 hours for the beta-phase. The main excretion products are: thiamine carbonic acid, pyramine, thiamine and a number of metabolites not yet identified. The greater the thiamine intake the more unchanged thiamine is excreted via the kidneys within 4 – 6 hours. The body stores approx. 30 mg. On account of the high turnover rate the reserve capacity (4 -10 days) is very limited.

Pyridoxine

Pyridoxine, pyridoxal and pyridoxamine are mainly rapidly absorbed in the upper gastrointestinal tract and are excreted with a maximum between 2 and 5 hours. The main excretion product is 4-pyridoxic acid. The function as a coenzyme depends on phosphorylation of the CH2-OH group at the 5 position (PALP). PALP is almost 80 % protein-bound in the blood. The body's vitamin B6

store amounts to between 40 and 150 mg, daily renal excretion amounts to 1.7 - 3.6 mg and the daily turnover rate is 2.2 to 2.4 %.

Cynocobalamin

Absorption of vitamin B12 from the gastrointestinal tract takes place by two mechanisms:
- the vitamin B12 taken up in the diet is released by the gastric acid and immediately bound to the intrinsic factor to form the actual vitamin B12 intrinsic factor complex
- independently of the intrinsic factor vitamin B12 may passively enter the bloodstream by way of an unspecific mechanism.

According to studies in healthy persons a maximum of 1.5 µg of vitamin B12 administered orally is absorbed by way of the intrinsic factor. When the oral dose is increased, a saturation point is reached in the intrinsic factor-dependent uptake and there is an increase in diffusion-induced absorption of vitamin B12. In patients with pernicious anaemia absorption rates of 1 % have been found after oral doses of 100 µg and over.

The vitamin B12 contained in the body is stored in depots, the liver being the most important of these.

The vitamin B12 used up by the daily requirement is very low; it Neurobion s.c.tabs SPC - MA Transfer - 5 - amounts to about 1 µg. The turnover rate is 2.5 µg B12 per day or 0.05 % of the total stores in the body.

Vitamin B 12 is mainly secreted in the bile and for the most part is reabsorbed via the enterohepatic circulation. If the storage capacity of the body is excreted by high doses of the vitamin, in particular in parenteral doses, the portion which is not retained is excreted in the urine.

The bioavailability of Neurobion, Art. No. 304 (coated tablet) was investigated versus Neurobion, Art. N o. 302 (injection solution, i .m. a dministration). P arenteral a dministration of t he vi tamin combination pr oduces h igher s erum l evels of t he vitamin than oral a dministration. Use of parenteral vitamin B1, B6 and B12 formulations is therefore particularly appropriate at the start of therapy. In this connection it is necessary to consider the fact that in diabetics or alcoholics - who make up t he l arger pa rt of pa tients w ith pol yneuropathy - gastrointestinal di sorders a re o ften present which may also affect absorption of vitamins given orally. There is no n egative effect on the phar macokinetic p roperties o f the indi vidual vi tamins a fter c ombined a dministration of vitamin B1, B6 and B12.

4.14 Preclinical safety data

No relevant data.

5. PHARMACEUTICAL PARTICULARS:

5.1 List of Excipients:

Dibasic Calcium Phosphate, Croscarmellose Sodium, Polyvinylpyrrolidone K-30, Starch, Lactose, Isopropyl A lcohol, T alcum, M agnesium S tearate, C rospovidone, B leached S hellac, M ethyl Paraben, P ropyl P araben, H ydroxypropylmethyl Cellulose, P olyethylene Glycol 6000, T itanium Dioxide, Colour Lake of Erythrosine, Purified Water.

5.2 Incompatibilities: None

5.3 Shelf life: 36 months from the date of manufacture.

5.4 Special precautions for storage: Do not store above 30°C.

5.5 Nature and contents of container:

Strip pack of 2 x 10's

5.6 Special precautions for disposal and other handling:

Any unused product or waste material should be disposed of in accordance with local requirements.

6. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS:

Marketing Authorization holder:

Centaur Pharmaceuticals Pvt. Ltd.

Manufacturing Site address:

Centaur Pharmaceuticals Pvt. Ltd.

Address: Plant: I, Plot No: 3, Tivim Industrial Estate, Karaswada, Mapusa Goa-403526

7. MARKETING AUTHORISATION NUMBER

176

8. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

27/05/1987

9. DATE OF REVISION OF THE TEXT: July 2019

10. DOSIMETRY (IF APPLICABLE): NOT APPLICABLE.

11. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

NOT APPLICABLE.