SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Neurocobal 500 mcg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:
Methylcobalamin USP…500 mcg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Neurocobal tablets are indicated for peripheral neuropathies and megaloblastic anemia caused by Vitamin B12 deficiency.

4.2 Posology and method of administration

Posology

For oral use

The dosage for clinical effect is 1500-6000 mcg per day. No significant therapeutic advantage appears to occur from dosages exceeding this maximum dose. Methylcobalamin has been administered orally, intramuscularly, and intravenously; however, positive clinical results have been reported irrespective of the method of administration. It is not clear whether any therapeutic advantage is gained from the non- oral methods of administration.

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

Caution should be exercised in patients with history of liver disease, any allergy, during pregnancy and breastfeeding.

Keep out of reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Chloramphenicol
Limited case reports suggest that chloramphenicol can delay or interrupt the reticulocyte response to supplemental Vitamin B12 in some patients. Monitor blood levels carefully if the combination cannot be avoided.
Absorption: The following medicines can reduce the absorption of Vitamin B12: aminosalicylic acid, antibiotics, colchicine, cholestyramine, H2 blockers, metformin, neomycin, nitrous oxide, oral contraceptives, phenytoin, phenobarbital, primidone, proton pump inhibitor, zidovudine.

4.6 Fertility, pregnancy and lactation

Vitamin B12 is likely safe for pregnant or breast-feeding women when taken by mouth in the amounts recommended. The recommended amount for pregnant women is
2.6 mcg per day. Breast-feeding women should take no more than 2.8 mcg per day. Don't take larger amounts. The safety of larger amounts is unknown.

4.7 Effects on ability to drive and use machines

There are no data about unfavourable influence on the active attention, reflexes and motor activity.

4.8 Undesirable effects

In some people, vitamin B12 might cause diarrhoea, blood clots, itching, serious allergic reactions, and other side effects.

Vitamin B12 also appears to be safe when used on the skin for psoriasis. Mild itching has been reported in one person who used a specific avocado oil plus vitamin B12 cream for psoriasis.

- irritability
- insomnia
- sore muscles
- achy joints
- acne
- rash
- severe anxiety
- palpitations
- nausea
- headaches
- migraines

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 EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

Treatment should be symptomatic and supportive.
In the case of accidental overdose of the product, contact the nearest hospital or poison control centre.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vitamin B12 (cyanocobalamin and analogues). Mecobalamin, ATC code: B03BA05

Methylcobalamin is an essential water-soluble vitamin B also known as vitamin B12. Vitamin B12 is required for nuclear-protein and myelin synthesis, cell reproduction, normal growth, and normal erythropoiesis. Vitamin B12 is converted to coenzyme B12, which is essential for the conversion of methylmalonate to succinate, and the synthesis of methionine from homocysteine. Vitamin B12 is involved in maintaining sulfhydryl groups in the reduced form required by enzymes involved in fat and carbohydrate metabolism, and protein synthesis. Vitamin B12 is involved in folate synthesis and a deficiency of methylcobalamin results in a functional folate deficiency. Vitamin B12 is required as part of the remethylation of homocysteine to methionine. Elevated levels of homocysteine has been

linked to the increase risk of endothelial cell damage, impaired endothelial- dependent vasodilation due to reduced nitric oxide activity, increased oxidation and arterial deposition of low-density lipoproteins (LDL), increased platelet adhesiveness, and activation of the clotting cascade. Vitamin B12 supplements have a small additive effect to folic acid in lowering fasting homocysteine levels, but probably only in people with vitamin B12 deficiency. Elevated homocysteine concentrations are possibly associated with other conditions such as decreased cognitive function, impaired memory, Alzheimer's disease, and vascular dementia. The methylcobalamin form of vitamin B12 might also influence melatonin levels. Methylcobalamin seems to improve alertness and reduce sleep time in humans with normal sleep patterns, possibly due to effects on melatonin.

The authority/EFDA will review new information on this medicinal product at least every year and this SmPC will be updated as necessary.>

5.2 Pharmacokinetic properties

Vitamin B12 is absorbed via an active transport mechanism in the terminal ileum. This requires the glycoprotein, intrinsic factor, which is produced by the stomach. At normal gastric pH, vitamin B12 is cleaved from proteins in food. It then binds to intrinsic factor and is absorbed by ileal transport. Absorption may be reduced by increased gastric pH such as atrophic gastritis, use of acid-suppressing drugs, or partial gastrectomy. The half-life of vitamin B12 is 6 hours and is secreted mainly via the bile.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose, Pregelatinised starch, Povidone, Isopropyl alcohol, Colloidal silicon dioxide, Purified Talc, Stearic acid, Ethyl cellulose, Titanium dioxide, Polyethylene glycol, Dichloromethane, Opadry brown 03F565012.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 30°C. Protect from light & moisture.
Keep all medicines out of reach of children.

6.5 Nature and contents of container

- PVC/PVDC opaque red blister of 10 tablets. 1 such blister of 10 tablets is packed in a carton along with packaging insert (1x10).
- 1 blister of 10 tablets is packed in a carton along with packaging insert. 10 such cartons are packed in an outer carton (10x1x10).
- PVC/PVDC opaque red blister of 10 tablets. 3 such blisters of 10 tablets are packed in a carton along with packaging insert (3x10).

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7. MARKETING AUTHORISATION HOLDER

Kusum Healthcare Pvt. Ltd.
SP-289(A), RIICO Industrial Area,
Chopanki, Bhiwadi, Dist. Alwar, Rajasthan, India

8. MARKETING AUTHORISATION NUMBER(S)

05240/07069/NMR/2018

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07 August 2020

10. DATE OF REVISION OF THE TEXT

08/2023

11. REFERENCES

SmPC published on electronic medicines compendium
https://www.medicines.org.uk/emc#gref

The MHRA published product information
https://products.mhra.gov.uk/

Human medicine European public assessment report
https://www.ema.europa.eu/en/medicines