SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Cyanocobalamin 50 microgram film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 50 microgram Cyanocobalamin.

Excipient with known effect:

Lactose 217.45mg per tablet

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

White to off white, (8.60mm) round, biconvex film coated tablet, plain on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Recommended Clinical Indications:

Treatment of nutritional Vitamin B12 deficiency.

Treatment of vitamin B12 deficiency following partial gastrectomy.

Treatment of tropical sprue, alone or with folic acid.

Treatment of pernicious anaemia when parenteral administration is not possible or not advised.

4.2 Posology and method of administration

Posology

Dosage:

Adults: - One to three tablets (50 to 150 micrograms).

In pernicious anaemia intramuscular therapy is preferable for initial correction of vitamin B_{12} deficiency. However, if necessary, the oral route may be used to follow this, in which case at least 300 micrograms should be given daily.

Elderly: - The normal dose for adults is appropriate for the elderly.

Children: - One tablet (50 micrograms) daily.

When possible, this medicine doses should be taken between meals. The dosage may be adjusted at the discretion of the physician.

Method of administration

Oral

4.3 Contraindications

Hypersensitivity to the product or any of the excipients.

4.4 Special warnings and precautions for use

For pernicious anaemia, an adequate dose must be used and the blood picture must be examined regularly at least every three months for 18 months until stabilised, and then annually.

Indiscriminate administration of this medicine may mask precise diagnosis.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine because it contains lactose.

4.5 Interaction with other medicinal products and other forms of interaction

Absorption may be reduced by Para-aminosalicylic acid, colchinine, biguanides, neomycin, cholestyramine, potassium chloride, methyldopa, and cimetidine.

Patients treated with chloramphenicol may respond poorly to this medicine.

Serum levels of this medicine may be lowered by oral contraceptives. These interactions are unlikely to have clinical significance.

Anti-metabolities and most antibiotics invalidate vitamins B12 assays by microbiological techniques.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is limited data from the use of cyanocobalamin in pregnant women. This medicine

should not be used to treat megaloblastic anaemia of pregnancy because this is due to folate

deficiency.

Breastfeeding

There is no data of the level of excretion of cyanocobalamin to human milk. A decision must be made whether to discontinue breast-feeding or to abstain from cyanocobalamin therapy taking

into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility

There is no information of the effects of cyanocobalamin on fertility.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Sensitisation to this medicine is rare, but may present as an itching exanthema, and exceptionally as anaphylactic shock.

Acneform and bullous eruptions have been reported rarely.

Patients who have become sensitised to this medicine by injection are often able to tolerate the oral route without trouble.

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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

Overdosage is unlikely to require treatment.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antianimic preparation, ATC code: B03BA01

This medicine contain cyanocobalamin vitamin B12, which is used for the treatment of pernicious anaemia, and nutritional deficiencies of vitamin B12 which results in macrocytic anaemia.

5.2 Pharmacokinetic properties

Absorption

The absorption of cobalamins from the gut is dependent upon the glycoprotein intrinsic factor.

Distribution

Cobalamins are transported rapidly into the blood bound to protein, known as transcobalamins.

Elimination

Cobalamins are stored in the liver and excreted in the bile.

They are known to cross the placenta.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Magnesium Stearate
Film coat contains
Hypromellose (E464)
Titanium dioxide (E171)
Talc
Polysorbate 80 (E433)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Blister: Store in the original package in order to protect from light.

6.5 Nature and contents of container

Clear PVC/PVdC /Aluminium blister pack contains 50 Tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

Relon Chem Ltd
Cheshire House, Gorsey lane,
Widnes, WA8 ORP,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 20395/0342

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03/11/2023

10 DATE OF REVISION OF THE TEXT

03/11/2023