

CYANOCOBALAMIN

G-COB

1 mg Film-Coated Tablet
VITAMIN



FORMULATION:

Each film-coated tablet contains:
Cyanocobalamin (Vit. B12) 1 mg

PRODUCT DESCRIPTION:

Red coloured, circular, biconvex, film coated tablet.

PHARMACOLOGICAL PROPERTIES:

Pharmacodynamic properties:

Pharmacotherapeutic group: Antianemic Preparations, Vitamin B12 (cyanocobalamin and analogues).

ATC code: B03BA01

Vitamin B12 is essential in humans and is primarily active in two important enzyme reactions. The adenosylating form is the co-factor to the mitochondrial enzyme methyl malonate mutase. This reaction is significant for normal lipometabolism. The methylated form of vitamin B12 is the co-factor for methionine synthetase and therefore essential for normal cell division. Lack of methylcobalamin is also considered to underlie demyelination as seen in vitamin B12 deficiency. A disturbance of this system leads to abnormal DNA metabolism with symptoms primarily from organs with rapid cell division, such as bone marrow and mucosa. It has been shown experimentally that a lack of the methylating form is accompanied by neurological damage.

Pharmacokinetic properties:

Orally administered cyanocobalamin is absorbed passively in the duodenum and small intestines even without the presence of intrinsic factor. The degree of absorption is dose-dependent and is about 1% of a dose of 1 mg or 10–12 µg after one Cyanocobalamin tablet. This dose is sufficient for the maintenance treatment of patients with pernicious anaemia and other forms of malabsorption of vitamin B12. Oral therapy with higher doses can be given initially, but in cases of manifest B12 deficiency, parenteral therapy should be preferred for faster remission and liver repletion.

INDICATIONS:

Vitamin B12 preparations are used in the treatment and prevention of B12 deficiency. Deficiency leads to the development of megaloblastic anaemias, and demyelination and other neurological damage. And treatment of pernicious anaemia.

DOSAGE AND ADMINISTRATION:

1-2 tablets daily until blood count returns to normal. Maintenance doses of 1 mg are administered. Or as prescribed by the physician.

CONTRAINDICATIONS:

Allergic hypersensitivity reactions have occurred rarely following the administration of Vitamin B12.

Vitamin B 12 should, if possible, not be given to patients without first confirming the diagnosis and should not be used for the treatment megaloblastic anaemia of pregnancy. Administration of doses of MORE than 10 micro grams daily may produce a haematological response in patients with folate deficiency.

FERTILITY, PREGNANCY AND LACTATION:

Pregnancy:

There are no known risks with use during pregnancy.

Breastfeeding:

Cyanocobalamin is excreted into human milk, but at therapeutic doses of Cyanocobalamin no effects on the breastfed newborns/infants are anticipated.

Effects on ability to drive and use machines:

Cyanocobalamin has no or negligible influence on the ability to drive and use machines.

ADVERSE DRUG REACTIONS:

Rare (1/10,000 to <1/1,000)

Immune system disorders: Anaphylaxis. Fever.

Skin and subcutaneous tissue disorders: Urticaria Exanthema. Exanthematous rash. Allergic reactions, including skin reactions and angioedema.

DRUG INTERACTIONS:

Absorption of Vitamin B12 from gastro intestinal tract may be reduced by aminoglycosides, aminosalicyclic acid, neomycin, H2-blockers, anticonvulsants, biguanides, chloramphenicol, colchicines and methyl dopa. Serum concentration may be decreased by concurrent administration of oral contraceptives.

The health and medical information provided here is intended to supplement and not substitute for the expertise and judgement of your physician, pharmacist or other health care professional. It should not be understood to indicate that the use of Vitamin B12 is safe, appropriate or effective for you. Always consult your health care professional before using this, or any other drugs.

OVERDOSE AND TREATMENT:

Toxicity:

Low acute toxicity.

Symptoms:

None expected, even after very high doses.

Treatment:

Should not be required.

Symptomatic treatment might be necessary, in exceptional cases.

CAUTION:

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to FDA: www.fda.gov.ph. Seek medical attention immediately at the first sign of any adverse drug reaction.

STORAGE CONDITION:

Store at temperatures not exceeding 30°C.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

AVAILABILITY:

Alu/PVC Blister Pack x10's (Box of 100's)

DR-XY47295

Date of First Authorization: June 7, 2021

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Manufactured by:

GLOW PHARMA PVT. LTD.

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