

pharmaniaga

Cyanocobalamin

100mcg/mL Injection



COMPOSITION:

Each 1mL ampoule contains 100mcg Cyanocobalamin.
Contains no preservative.

DESCRIPTION:

A clear and red coloured solution. Single dose container.

ACTION AND MODE OR MECHANISM OF ACTION:

Vitamin B12 acts as coenzyme for various metabolic functions, including fat and carbohydrate metabolism and protein synthesis. It is necessary for growth, cell replication, haematopoiesis and nucleoprotein and myelin synthesis, largely due to its effects on metabolism of Methionine, Folic Acid and Malonic Acid.

PHARMACOLOGY:

Vitamin B12 is metabolised in the liver and has a half-life of approximately 6 days. It is excreted through the biliary system, largely unchanged in urine.

TOXICOLOGY:

Over dosage is quite unlikely with Vitamin B12 in patients with normal kidney function.

INDICATIONS:

Vitamin B12 is indicated for treatment of Vitamin B12 deficiency. Vitamin B12 deficiency may occur as a result of inadequate nutrition or intestinal malabsorption but does not occur in healthy individuals receiving adequate balanced diet. However, simple vitamin B12 deficiency may occur in strict vegetarians and their breast-fed infants since Vitamin B12 is found in animal protein and not in vegetables. Dietary sources are preferred over supplementation whenever possible. Vitamin B12 is also indicated for treatment of pernicious anaemia (due to lack or inhibition of intrinsic factor).

CONTRAINDICATIONS:

Leber's disease.

SIDE EFFECTS / ADVERSE REACTIONS:

Water soluble vitamin seldom causes toxicity in persons with normal renal function. However, skin rash, itching or wheezing may occur in patients who are allergic to it.

PRECAUTIONS / WARNINGS:

Cyanocobalamin Injection should not be administered intravenously, although small amounts of Cyanocobalamin are sometimes included in Total Parenteral Nutrition (TPN) solutions.

RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION:

Usual adult dose : For treatment of Vitamin B12 deficiency :

– Initial IM or SC 100mcg per day for 6 or 7 days followed by 100mcg every other day for seven doses if clinical improvement and reticulocyte response occur then 100mcg every three or four days for another two to three weeks.

For the treatment of pernicious anaemia :

– 250 to 1000mcg IM each month.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE AND ANTIDOTES(S):

Over dosage with Cyanocobalamin is quite unlikely.

STORAGE CONDITIONS, USER INSTRUCTIONS AND PHARMACEUTICAL PRECAUTIONS:

Store below 30°C . Protect from light.

Do not use if solution contains growth, particles, turbidity or if there is any change of appearance.

SHELF LIFE:

2 years from date of manufacture.

PRESENTATION:

10 x 1mL ampoule (amber).

PRODUCT REGISTRATION HOLDER/MANUFACTURER:

PHARMANIAGA LIFESCIENCE SDN BHD (82685-T)

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PM240.3

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