December 2023

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE MEDICINAL PRODUCT

CYNOVIT (Cyanocobalamin (Vitamin B_{12}) 1000mcg/mL Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule contains 1.00 mg Cyanocobalamin (Vitamin B_{12})

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Ampoules for Injection.

Clear red solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Cynovit is indicated in the following:

- Addisonian pernicious anaemia.
- Prophylaxis and treatment of other macrocytic anaemia's associated with vitamin B_{12} deficiency.
- Schilling test.

It is not indicated for treatment of toxic amblyopias

4.2 Posology and method of administration

Route of administration: Intramuscular administration.

Adults and Children

- Addisonian pernicious anaemia and other macrocytic anaemia's without neurological involvement:
  - Initially: 250 to 1000mcg intramuscularly on alternate days for one to two weeks, then 250mcg weekly until the blood count is normal.
  - Maintenance: 1000mcg monthly.
- Addisonian pernicious anaemia and other macrocytic anaemia's with neurological complications:
  - Initially: 1000mcg intramuscularly on alternate days as long as improvement is occurring.
  - Maintenance: 1000mcg monthly.
- Prophylaxis of macrocytic anaemia associated with vitamin B_{12} deficiency resulting from gastrectomy, some malabsorption syndromes and strict vegetarianism:
  - 250mcg - 1000mcg monthly
- Schilling Test:
  - An intramuscular injection of 1000mcg cyanocobalamin is an essential part of this test.

4.3 Contraindications

- Hypersensitivity to cyanocobalamin or any other constituents
- Cyanocobalamin should not be used for the treatment of megaloblastic anaemia of pregnancy unless vitamin B_{12} deficiency has been demonstrated.

- Not indicated for treatment of toxic amblyopias

4.4 Special warnings and precautions for use

The dosage schemes given above are usually satisfactory, but regular examination of the blood is advisable. If megaloblastic anaemia fails to respond to cyanocobalamin, folate metabolism should be investigated. Doses in excess of 10mcg daily may produce an incomplete haematological response in patients with folate deficiency. Indiscriminate administration may mask the true diagnosis. The haematological and neurological state should be monitored regularly to ensure adequacy of therapy. Cardiac arrhythmias secondary to hypokalaemia during initial therapy have been reported. Plasma potassium should therefore be monitored during this period. Platelet count should be monitored during the first weeks of use in megaloblastic anaemia due to the possible occurrence of reactive thrombocytosis.

4.5 Interaction with other medicinal products and other forms of interaction

Chloramphenicol-treated patients may respond poorly to cyanocobalamin. Serum concentrations of cyanocobalamin may be lowered by oral contraceptives but this interaction is unlikely to have clinical significance.
Antimetabolites and most antibiotics invalidate vitamin B_{12} assays by microbiological techniques.

4.6 Pregnancy and lactation

Cyanocobalamin should not be used for the treatment of megaloblastic anaemia of pregnancy unless vitamin B_{12} deficiency has been demonstrated. Cyanocobalamin is secreted into breast milk but this is unlikely to harm the infant, and may be beneficial if the mother and infant are vitamin B_{12} deficient.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Hypersensitivity reactions have been reported including skin reactions (e.g. rash, itching) and exceptionally anaphylaxis. Other symptoms reported include fever, chills, hot flushing, dizziness, malaise, nausea, acneiform and bullous eruptions, tremor and injection site reactions including injection site pain, injection site induration and injection site necrosis. Reactive thrombocytosis can occur during the first weeks of use in megaloblastic anaemia.

Healthcare professionals are asked to report any suspected adverse reactions via:
Pharmacovigilance and Medical Device Section
Drug Department - U.A.E M.O.H
Hotline: 80011111
Email: pv@moh.gov.ae
P.O. Box: 1853 Dubai U.A.E.

4.9 Overdose

Treatment is unlikely to be needed in cases of overdosage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cyanocobalamin is a form of vitamin B_{12}.

5.2 Pharmacokinetic properties

Cobalamins are absorbed from the gastro-intestinal tract, but may be irregularly absorbed when given in large therapeutic doses. Absorption is impaired in patients with an absence of intrinsic factor, with a malabsorption syndrome or with a disease or abnormality of the gut, or after gastrectomy.
After injection of cyanocobalamin a large proportion is excreted in the urine within 24 hours; the body retains only 55% of a100-microgram dose and 15% of a 1000 microgram dose. Vitamin B_{12} is extensively bound to specific plasma proteins called transcobalamins; transcobalamin II appears to be involved in the rapid transport of the cobalamins to tissues. Vitamin B_{12} is stored in the liver, excreted in the bile, and undergoes extensive enterohepatic recycling; part of an administered dose is excreted in the urine, most of it in the first 8 hours; urinary excretion, however, accounts for only a small fraction in the reduction of total body stores acquired by dietary means. Vitamin B_{12} diffuses across the placenta and also appears in breast milk.

5.2 Preclinical safety data

None stated

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glacial acetic acid
Sodium acetate trihydrate
Sodium chloride
Sodium hydroxide pellets
Water for injection
Nitrogen gas

6.2 Incompatibilities

None

6.3 Shelf life

24 months from the date of manufacturing.

6.4 Special precautions for storage

Store below 30ºC, protected from light and heat.

6.5 Nature and contents of container

1mL injection in amber coloured glass ampoule, 5 ampoules in a ampoule tray, packed in a printed carton along with a leaflet.

6.6 Special precautions for disposal and other handling

None stated

7. MARKETING AUTHORIZATION HOLDER

Gulf Pharmaceutical Industries - Julphar
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Ras Al Khaimah - United Arab Emirates
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8. MARKETING AUTHORIZATION NUMBER

3426-4401-1

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

28. June. 1998

10. DATE OF REVISION OF THE TEXT

09. April. 2019