

COBAL[®]

DESCRIPTION

COBAL is the trade name of Mecobalamin, a naturally occurring Vitamin B12 substance, used in the treatment of pernicious anemia and other vitamin B12 deficiency states as well as peripheral neuropathies.

- Each Film-Coated **COBAL** 500 µg Tablet contains Mecobalamin 500 µg.
- Each **COBAL** 500 µg Orodispersible Tablet (ODT) contains Mecobalamin 500 µg.
- Each **COBAL** Injection contains Mecobalamin 500 µg.

Excipients:

- **COBAL** Film- Coated Tablet: lactose, maize starch, povidone K 30, magnesium stearate, hydroxypropyl methylcellulose type 2910, titanium dioxide, polyethylene glycol 400, white bees wax.
- **COBAL** Orodispersible Tablet (ODT): pharaburst C1, croscarmellose sodium, aspartame, povidone 30, cherry powder, magnesium stearate.
- **COBAL** Injection: mannitol (pyrogen free), water for injection.

CHEMISTRY

Mecobalamin is: Cobinamide, Co-methyl derivative, dihydrogen phosphate (ester), inner salt 3'-ester with 5,6-dimethyl-1- α -D-ribofuranosyl-1H-benzimidazole.

CLINICAL PHARMACOLOGY

Mecobalamin is a B12 coenzyme that occurs naturally in the blood and the cerebrospinal fluid. Mecobalamin is necessary for various metabolic functions, including fat and carbohydrate metabolism and protein synthesis, and is necessary for growth, cell replication, hematopoiesis and nucleoprotein and myelin synthesis, largely due to its effects on metabolism of methionine, folic acid, and malonic acid. In effect, Mecobalamin inhibits nerve fiber degeneration in case of neuropathy and accelerates the repair of nerve tissue, as demonstrated by animal studies. Accordingly Mecobalamin is useful in the treatment of numbness, pain, and paralysis due to peripheral neuropathies including diabetic neuropathy and polyneuritis.

Mecobalamin promotes the maturation and division of erythroblast and heme synthesis, thereby improving the blood picture in anemia. Clinically, Mecobalamin injection has been shown to benefit megaloblastic anemia and peripheral neuropathies such as diabetic neuropathy and polyneuritis. The increment in peak serum total vitamin B12 level was 22.4 ± 1.1 ng/ml after i.m. administration and 85.0 ± 8.9 ng/ml after i.v. administration. Orally, Mecobalamin is readily absorbed from the lower half of the ileum via the intrinsic factor.

INDICATIONS

- **COBAL** is indicated in the treatment of peripheral neuropathies.
- **COBAL** Injection is also indicated in the treatment of megaloblastic anemia due to vitamin B12 deficiency.

DOSAGE

Usual adult oral dose:

One **COBAL** Tablet or **COBAL** ODT Tablet three times daily. Dosage may be adjusted according to patient's age and clinical response.

Usual adult parenteral dose:

- Peripheral neuropathies: The usual dose for adults is 1 ampule (500 µg of Mecobalamin), administered intramuscularly (i.m.) or intravenously (i.v.) three times a week. The dose should be adjusted according to the age of patient and severity of symptoms.
- Megaloblastic anemia: The usual dose for adults is 1 ampule (500 µg of Mecobalamin), administered intramuscularly or intravenously three times a week. After approximately 2 months of medication, the dose should be reduced to a single administration one ampule at 1 to 3-month intervals for maintenance therapy.

Note:

Place **COBAL** ODT tablet on the tongue, allow it to dissolve and then swallow. No water is required. No need to chew.

ADVERSE EFFECTS

- Mecobalamin is well tolerated. Only rarely gastrointestinal symptoms such as anorexia, nausea, vomiting and diarrhea occur. Skin rash may also rarely occur.
- Pain and induration may infrequently occur at the site of intramuscular injection, and headache, sweating or hot sensation may rarely occur.

USE IN PREGNANCY

Studies have not been done in humans. In animals, Mecobalamin was not found teratogenic and no abnormal findings were observed in the fetuses and newborns after i.v. administration of Mecobalamin during the perinatal period.

USE IN LACTATION

Mecobalamin is distributed into breast milk. In animals, no abnormal findings were observed in the newborns after i.v. administration of Mecobalamin during the lactating period.

INTERFERENCE WITH CLINICAL AND LABORATORY TESTS

Methotrexate, pyrimethamine, and most anti-infectives invalidate diagnostic microbiologic blood assays for Vitamin B12 substances in general.

DRUG INTERACTIONS

No drug interactions of major clinical significance have been reported with Mecobalamin. However, the gastrointestinal absorption of Vitamin B12 substances in general may be decreased by colchicine, aminoglycoside antibiotics, aminosalicilic acid and its salts, and by excessive alcohol intake lasting longer than 2 weeks.

CONTRAINDICATIONS

Mecobalamin is contraindicated in patients with sensitivity to the drug, to cobalt, or to other Vitamin B12 substances, including cyanocobalamin and hydroxocobalamin.

WARNINGS

Not documented.

OVERDOSE

Vitamin B12 preparations in general are usually nontoxic, even in large doses.

PRECAUTIONS

- Individuals sensitive to other cobalamins (found naturally in foods) may be sensitive to Vitamin B12 substances also, including Mecobalamin.
 - The efficacy of Mecobalamin should be assessed after several months of treatment. The drug should be discontinued if no response has been achieved.
 - The use of Mecobalamin is not recommended in patients handling mercury or mercury derivatives.
 - **COBAL** Injection should be discontinued if symptoms of hypersensitivity, such as skin eruptions, occur.
 - **COBAL** is susceptible to photolysis. The Injection must be used promptly after the package is opened, and care must be taken not to expose the ampules to direct light.
 - In intramuscular administration, care should be exercised, by following the instructions mentioned below, to avoid adverse effects on tissues or nerves.
 - Repeated injection at the same site should be avoided. particular care should be exercised when administering this drug to neonates, premature infants, infants and children.
 - The course of nerves should be avoided for the site of injection.
 - If the patient complains of a severe pain or if blood reflux occurs when the syringe needle is stuck, withdraw it immediately and try at a different site.
- The ampule of **COBAL** is a one-point-cut type. It is recommended that the cut point of the ampule be wiped clean with an alcohol swab before opening.

Important information about some of the ingredients of COBAL

COBAL Tablets:

COBAL tablets contain lactose. If the patient has intolerance to some sugars, the patient should contact doctor before taking this medicinal product.

COBAL Orodispersible Tablets:

COBAL orodispersible tablets contain aspartame, a source of phenylalanine. If the patient has phenylketonuria (a rare, hereditary disorder of the metabolism), the patient should take into account that each **COBAL** orodispersible tablet contains phenylalanine.

HOW SUPPLIED

- Boxes of 30 stripped Tablets of **COBAL** 500 µg Tablets.
- Boxes of 105 stripped Tablets of **COBAL** 500 µg Tablets.
- Bottles containing 30 Orodispersible Tablets of **COBAL** ODT 500 µg.
- Boxes of 8 Ampules of **COBAL** 500 µg Injection.
- Hospital packs of different presentations.

STORAGE CONDITION

- **COBAL** tablet and **COBAL** Orodispersible tablet: Do not store above 30°C, protected from light and humidity.
- **COBAL** injection: Store below 30°C, protected from light.
- Do not use after the expiry date shown on the package.

Health care professionals and patients are encouraged to report adverse events or side effects to JFDA by using:

Email: jpc@jfda.jo

Website: www.jfda.jo

Mobile application: (Jordan fda)

Yellow card form.

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THIS IS A MEDICAMENT



- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children.

COUNCIL OF ARAB HEALTH MINISTERS
UNION OF ARAB PHARMACISTS

Prescribing Information Available Upon Request



COBAL Tablets manufactured by: The Jordanian Pharmaceutical Manufacturing CO. / P.O.Box 151, Um Al - Amad 16197, Jordan

COBAL Injection: manufactured by: STERIPHARM - Tunis

Product license holder (Marketing Authorization Holder) for **COBAL** Injection: The Jordanian Pharmaceutical Manufacturing CO./ P.O.Box 151, Um Al - Amad 16197, Jordan