(ΔAUC) calculated by increment of the actual values at 144 hr. after administration was 204.1ng hr. /mL after intramuscular administration and 358.6ng hr. /mL after intravenous administration. On the other hand, the rate of binding saturation showed a similar increase in both groups of subjects for 144 hr. after administration.

(2) Intramuscular administration in intramuscular administration, the following precautions should be taken to avoid adverse effects on tissues or nerves: **(i)** avoid repeated injection at the same site. Particular caution should be exercised when administering the product to prematures, neonates, nursing infants and children. **(ii)** Do not inject in densely innervated site. **(iii)** If insertion of the injection needle causes intense pain or if blood flows back into the syringe, withdraw the needle immediately and inject at a different site.

ADVERSE EFFECTS & PRECAUTIONS

Allergic hypersensitivity reactions have occurred rarely after cyanocobalamin and hydroxocobalamin and include skin reactions such as rash and itching, and anaphylaxis. Patients who are hypersensitive to cyanocobalamin injection may be able to take oral cyanocobalamin. Antibodies to hydroxocobalamin-transcobalamin II complex have developed during hydroxocobalamin therapy. Arrhythmias secondary to hypokalaemia have occurred at the beginning of parenteral treatment with hydroxocobalamin. Injection site reactions including pain, erythema, pruritus, induration, swelling, and necrosis can occur. Intranasal cyanocobalamin may cause arthralgia, dizziness, headache, nasophatyngitis, and rhinitis; epistaxis has also been reported.

Other adverse effects reported with cyanocobalamin and hydroxocobalamin include gastrointestinal disturbances, fever, chills, hot flushing, dizziness, malaise, acneform and bullous eruptions, and tremor. Headaches, paraesthesia, and chromaturia have occurred with hydroxocobalamin. Cyanocobalamin or hydroxocobalamin should, if possible, not be given to patients with suspected vitamin B12 deficiencies without first confirming the diagnosis. Regular monitoring of the blood is advisable. Use of doses greater than 10 micrograms daily may produce a haematological response in patients with folate deficiency; indiscriminate use may mask the precise diagnosis. Conversely, folate may mask vitamin B 12 deficiency.

Cyanocobalamin should not be used for Leber's disease or tobacco amblyopia since these optic neuropathies may degenerate further.

INTERACTIONS

Absorption of vitamin B12 from the gastrointestinal tract may be reduced by neomycin, aminosalicylic acid, histamine H2-antagonists, omeprazole, and colchicine. Serum concentrations may be decreased by use of oral contraceptives. Many of these interactions are unlikely to be of clinical significance but should be taken into account when performing assays for blood concentrations. Parenteral chloramphenicol may attenuate the effect of vitamin B 12 in anaemia.

Pregnancy: - There are no data available for Methylcobalamin to be used in pregnant women.

Lactation: - There are no data available for Methylcobalamin to be used in lactating women. However, since vitamin B12 is distributed into breast milk, The American Academy of Pediatrics considers its use to be usually compatible with breast feeding.

OVER-DOSAGE:

There have been no reports, in the literature, of overdosage with Methylcobalamin.

PRECAUTION FOR HANDLING

Mecobalamin Injection is packaged in the LPE pack (Light Protect Easy open pack) to ensure quality during storage. The LPE pack should be opened immediately before using.

Storage : Store in a cool, dry & dark place.Protect from direct light.

Improper storage may deteriorate the product.

Medicine : Keep out of reach of children.

Presentation : 1 ml PFS pack along with pack insert.

Manufactured by:

AMERICAN REMEDIES©
Care & Cure with Research

American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
ICO: American Remedies LLC, DE, USA
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WHO GMP CERTIFIED

Scan for Batch Certificate

For the use only of a Registered Medical Practitioner or a hospital or a laboratory

Mecobalamin Injection 1500 mcg

AMERICAN
COBAMAX AQ 1500 PFS
Injection

(Light Sensitive) for I.M./I.V. / S.C use only

Composition :

Each Pre-Filled Syringe contains :

Mecobalamin	I.P.	1500 mcg
Benzyl Alcohol (As Preservative)	I.P.	2% v/v
Water for Injection	I.P.	q.s.

Appropriate overage of vitamins are added to compensate any loss on storage.

DESCRIPTION:-

Mecobalamin Injection is a clear, red injection containing Mecobalamin, it contained in amber ample,

Mecobalamin occurs as dark red crystals or crystalline powder. It is sparingly soluble in water, slightly soluble in ethanol (99.5), and practically insoluble in acetonitrile. It is affected by light. Chemical name: Co α-[α-(5, 6-Dimethylbenz-1H-imidazolyl)]-Coβ Mecobalamin Molecular formula: $C_{63}H_{91}CON_{1}$ Q P. Mecobalamin is a type of Vitamin B_{12}

PHARMACOLOGY

PHARMACOKINETICS

Vitamin B_{12} substances bind to intrinsic factor; glycoproteins secreted by the gastric mucosa, and are then actively absorbed from the gastrointestinal tract. Absorption is impaired in patients with an absence of intrinsic factor, with a malabsorption syndrome or with disease or abnormality of the gut, or after gastrectomy. Absorption from the gastrointestinal tract can also occur by passive diffusion; little of the vitamin present in food is absorbed in this manner although the process becomes increasingly important with larger amounts such as those used therapeutically. After intranasal dosage, peak plasma concentrations of cyanocobalamin have been reached in · 1 to 2 hours. The bioavailability of the intranasal preparation is about 7 to 11 % of that by intramuscular injection. 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 a 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.

RETENTION IN THE BODY

A short review1 in 1984 noted that after injection of Vitamin B12 a large proportion was excreted in the urine within 24 hours; the body retained only 55 % of a 100-microgram dose and 15 % of a 1000-microgram dose. Body stores of vitamin B12 amounted to 2000 to 3000 micrograms which was believed to be enough for 3 to 4 years. If 1000 micrograms is injected monthly, the 150 micrograms retained lasts for about 1 month. Hydroxocobalamin was better retained than cyanocobalamin; the review stated that 90% of a 100-microgram dose and 30 % of a 1000-microgram dose were retained which was believed to be enough for 2 to 10 months.

DOSAGE AND ADMINISTRATION

Mecobalamin is susceptible to photolysis and the ampoules are packaged in the light-proof packaging to ensure the quality during storage. If ampoules are not kept in the light-proof packaging, methylcobalamin decomposes by light and the content decreases. Therefore, this product should be used promptly after the package is opened, and caution should be taken so as not to expose the ampoules to direct light.

(1) **Single-dose administration**:- When Mecobalamin was administered intramuscularly or intravenously to 12 healthy adult male volunteers at a single dose of 500 μg, the time to reach peak serum total vitamin B12 concentration (tmax) was 0.9 hr. after intramuscular administration and immediately to 3 min after intravenous administration, and the increment (except endogenous serum total B12) in peak serum total vitamin B12 concentration (ΔCmax) was 22.4 ng/mL after intramuscular administration and 85.0 ng/mL after intravenous administration. The area under the serum total B12 concentration- time curve