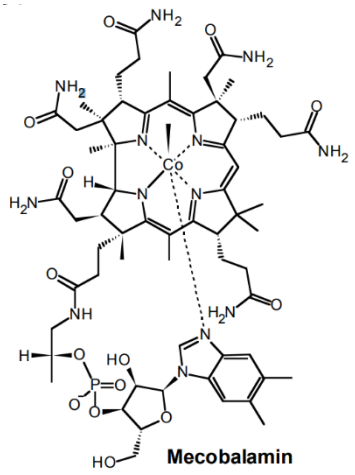
Nevitix
(Mecobalamin)
500mcg I.M. / I.V. Injection

نیوی ٹیکس ۵۰۰ مائیکروگرام
(میکوبال امین) (رویدی اور عضلاتی) انجکشن

500mcg Injection

1. DESCRIPTION :

Nevitix (Mecobalamin) is a B12 containing coenzyme with an active methyl base. It plays an important role in red blood cell formation, methylation reaction, brain and nervous system functions and immune system functions. Chemically, mecobalamin is described as α (5,6-Dimethylbenzimidazolyl)-Co-methyl-cobamide. The molecular formula is C63H91CoN13O14P and the structural formula is:



2 COMPOSITION:

Each 1ml Ampoule contains:
Mecobalamin ..... 500 mcg.
(As per Innovator's Specifications)

3 INDICATION:

Peripheral neuropathies
Megaloblastic anemia caused by vitamin B12 deficiency
<Precautions>
METHYCOBAL should not be used aimlessly for more than one month unless it is effective.

3 DOSAGE & ROUTE OF ADMINISTRATION

Peripheral neuropathies

The usual dosage for adults is 1 ampoule (500 µg of mecobalamin) per day, administered intramuscularly or intravenously 3 times a week. The dosage may be adjusted depending on the patient's age and symptoms.

Megaloblastic anemia

The usual dosage for adults is 1 ampoule (500 µg of mecobalamin) per day, administered intramuscularly or intravenously 3 times a week. After about 2 months of medication, the dose should be re- duced to a single administration of 1 ampoule at 1 to 3 months in- tervals for maintenance therapy.

4 PRECAUTIONS

Adverse Reactions

Adverse reactions were reported in 13 of 2,872 patients (0.45%). (At the end of the reexamination period)

(1) Clinically significant adverse reactions (incidence un- known)

Anaphylactoid reactions

Anaphylactoid reactions, such as decrease in blood pressure or dyspnea, may occur. Patients should be carefully observed. In the event of such symptoms, treatment should be discontinued immediately and appropriate measures taken.

(2) Other adverse reactions

	<0.1%	Incidence unknown
Hypersensitivity note)	Rash	
Others	Headache and hot sensation	Diaphoresis and pain / induration at the site of intramuscular injection

Note: In the event of such symptoms, treatment should be discontinued.

5 CONTRAINDICATION

Hypersensitivity to any form of vitamin B12

6. INTERACTIONS WITH OTHER MEDICAMENTS

Not applicable.

7. INCOMPATIBILITY

Not applicable.

8. STATEMENT ON USAGE DURING PREGNANCY AND LACTATION

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy. Clinical studies have been done on pregnant women and no harmful effects have been reported. Methycobal with the approved dosage can be used during pregnancy.

It has been shown that mecobalamin is excreted in the milk of lactating rats.

9. OVERDOSE AND TREATMENT

Experience to date with deliberate or accidental overdose is limited. No specific antidote is known. As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilised.

10. PRECAUTIONS CONCERNING USE

(1) Administration

METHYCOBAL is susceptible to photolysis. It should be used promptly after the package is opened, and caution should be taken so as not to expose the ampoules to direct light.

(2) Intramuscular administration

In intramuscular administration, caution should be exercised, by following the instructions mentioned below to avoid ad- verse effects on tissues or nerves.

1) Avoid repeated injection at the same site. Particular caution should be exercised when administering METHYCOBAL to prematures, neonates, nursing infants and children.

2) Do not inject in densely innervated site.

3) 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.

(3) Opening the ampoule

METHYCOBAL is supplied in one-point-cut ampoules. The cut point of the ampoules should be wiped with an alcohol swab before opening.

11. OTHER PRECAUTIONS

Mecobalamin contains cobalt and may cause sensitivity reactions in individuals with cobalt allergy.

12. SHELF LIFE

2 years

14. INSTRUCTION / STORAGE CONDITION

Store at 30°C.
Protect form light.
Keep out of reach of children.

Nevitix (Mecobalamin) injection is stored in LPE packs (Light Protect Easy open pack). Light protective packs ensures quality during storage. This pack should be opened only prior to use. If ampoules are kept out of the light protective packs (LPP) the drug will decompose upon exposure to light.

15. HOW SUPPLIED

Nevitix (Mecobalamin) 500mcg I.M./I.V. injection is available in blister Pack of 10x1mL ampoules.

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خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات: ۳۰ڈگری پر محفوظ کریں۔
روشنی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
دوا کی تاثیر کو برقرار رکھنے کے لئے دوا کو روشنی سے
بچانے والے مخصوص پیک میں رکھا گیا ہے۔
دوا کے پیک کو صرف استعمال سے پہلے کھولیں۔
صرف مُستند ڈاکٹر کے نسخے پر فروخت کی جائے۔

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Mfg. Lic. No.: 000442

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