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HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use M.V.I.-12™ Unit Vial (Multi-Vitamin Infusion without vitamin K) safely and effectively. See full prescribing information for M.V.I.-12™ Unit Vial (Multi-Vitamin Infusion without vitamin K).

M.V.I.-12™ Unit Vial (Multi-Vitamin Infusion without vitamin K) for dilution in intravenous infusions only.

Initial U.S. Approval: 1953

RECENT MAJOR CHANGES

Dosage and Administration (2.1) (2.3) (2.4)	03/2013
Warnings and Precautions (5)	03/2013

INDICATIONS AND USAGE

M.V.I.-12™ Unit Vial, is indicated for the prevention of vitamin deficiency in adults and children aged 11 years and above who are on warfarin anticoagulant therapy receiving home parenteral nutrition. (1)

DOSAGE AND ADMINISTRATION

M.V.I.–12™ is ready for immediate use in adults and children aged 11 years and above when added to intravenous infusion fluids. (2)

A number of the physical incompatibilities between M.V.I.–12™ infusion and drugs have been reported. The following are examples of these interactions (2.4):

- Acetazolamide
- Intravenous chlorothiazide sodium
- Aminophylline
- Ampicillin
- Moderately alkaline solutions
- Calcium salts such as calcium gluconate
- Vitamin K bisulfite or sodium bisulfite

DOSAGE FORMS AND STRENGTHS

M.V.I.–12™ Unit Vial is a sterile product in a two-chambered single-dose 10 mL vial which must be mixed just prior to use. (3)

CONTRAINDICATIONS

Hypersensitivity to any of the vitamins in this product or an existing hypervitaminosis. (4)

WARNINGS AND PRECAUTIONS

- This product contains aluminum that may be toxic. (5.1)
- Studies have shown that vitamin A may adhere to plastic, resulting in inadequate vitamin A administration in the doses recommended with M.V.I.–12™. (5.2)
- Do not add M.V.I.–12™ directly to intravenous fat emulsions. (5.3)
- Allergic reactions such as urticaria, periorbital and digital edema, have been reported following intravenous administration of thiamine. (5.4)
- Hypervitaminosis A has been reported in patients with renal failure receiving 1.5 mg/day retinol and in patients with liver disease. (5.5)
- Do not administer M.V.I.–12™ to patients with suspected or diagnosed megaloblastic anemia prior to the blood sampling for the detection of the folic acid and cyanocobalamin deficiencies. (5.6)
- Blood vitamin concentration should be periodically monitored to determine if vitamin deficiencies or excesses are developing. (5.7)
- Ascorbic acid in the urine may cause negative urine glucose determination. (5.8)

ADVERSE REACTIONS

There have been rare reports of the following types of reactions(6):

- Allergic — anaphylactoid reactions following large intravenous doses of thiamine, urticaria, periorbital and digital edema
- Dermatologic — rash, erythema, pruritus
- CNS — headache, dizziness, agitation, anxiety
- Ophthalmic — diplopia

To report SUSPECTED ADVERSE REACTIONS, contact Hospira, Inc. at 1-800-441-4100 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

DRUG INTERACTIONS

A number of interactions between vitamins and drugs have been reported. The following are examples of these interactions:

Physical Incompatibilities (7.1):

- Thiamine, riboflavin, pyridoxine, niacinamide, and ascorbic acid have been reported to decrease the antibiotic activity of erythromycin, kanamycin, streptomycin, doxycycline, and lincomycin.
- Bleomycin

Clinical Interactions:

- Phenytoin (7.1)
- Levodopa (7.1)
- Chloramphenicol (7.2)

USE IN SPECIFIC POPULATIONS

- Pregnant and Nursing Mothers: Pregnant women should follow the U.S. Recommended Daily Allowances for their condition, because their vitamin requirements may exceed those of nonpregnant women. (8.1, 8.3)
- Pediatric Use: Safety and effectiveness in children below the age of 11 years have not been established. (8.4)
- Monitor calcium and phosphorus levels in patients with renal impairment. (8.6)
- Monitor vitamin A level in patients with liver disease, high alcohol consumption. (8.7)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 03/2013

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FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION
- 2.1 Starting Dose, Dose Range and Route of Administration
- 2.2 Monitoring
- 2.3 Instructions for Intravenous Administration
- 2.4 Drug Incompatibilities

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS
- 5.1 Aluminum Toxicity
- 5.2 Adherence of Vitamin A to Plastic
- 5.3 Intravenous Fat Emulsions
- 5.4 Allergic Reactions to Thiamine
- 5.5 Hypervitaminosis A
- 5.6 Blood Sampling of Megaloblastic Anemia Patients
- 5.7 Monitor Blood Vitamin Concentrations
- 5.8 Interference with Urine Glucose Testing

6 ADVERSE REACTIONS

7 DRUG INTERACTIONS
- 7.1 Clinical Interactions Affecting Drug Levels
- 7.2 Clinical Interactions Affecting Vitamin Levels

8 USE IN SPECIFIC POPULATIONS
- 8.1 Pregnancy
- 8.3 Nursing Mothers
- 8.4 Pediatric Use
- 8.6 Patients with Renal Impairment
- 8.7 Patients with Liver Impairment

10 OVERDOSAGE

11 DESCRIPTION

13 NONCLINICAL TOXICOLOGY
- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

* Sections or subsections omitted from the full prescribing information are not listed

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

M.V.I.-12™ Unit Vial (Multi-Vitamin Infusion without vitamin K) is indicated for the prevention of vitamin deficiency in adults and children aged 11 years and above on warfarin anticoagulant therapy receiving parenteral nutrition.

The physician should not await the development of clinical signs of vitamin deficiency before initiating vitamin therapy.

2 DOSAGE AND ADMINISTRATION

M.V.I.–12™ is ready for immediate intravenous use in adults and children aged 11 years and above when added to intravenous infusion fluids. Do not administer M.V.I.-12™ as a direct, undiluted intravenous injection as it may cause dizziness, faintness, and tissue irritation.

2.1 Starting Dose, Dose Range and Route of Administration

The starting dose is one 10 mL daily dose added directly to an intravenous fluid. Patients with multiple vitamin deficiencies or with markedly increased requirements may need multiple daily dosages as indicated. Some patients do not maintain adequate levels of certain vitamins when this formulation in recommended amounts is the only source of vitamins.

2.2 Monitoring

Blood vitamin concentrations should be monitored to ensure maintenance of adequate levels, particularly in patients receiving parenteral multivitamins as the only source of vitamins for long periods of time.

2.3 Instructions for Intravenous Administration

The solution must be prepared prior to intravenous administration.

- Remove the protective plastic cap, turn the plunger-stopper 90° and press down firmly to force liquid in the upper chamber and the center seal into the lower compartment. Gently agitate to mix solution. Disinfect the rubber stopper in the usual manner before inserting needle squarely through the center of the plunger-stopper until tip is just visible. Vial should be mixed just prior to use. Invert vial and withdraw a 10 mL dose in the usual manner.
- Do not administer M.V.I.–12™ as a direct, undiluted intravenous injection as it may cause dizziness, faintness, and possible tissue irritation.
- Aseptically transfer each sterile 10 mL dose into a plastic or glass container containing at least 500-1000 mL of intravenous dextrose or saline.
- Withdraw container contents without delay.
- After M.V.I.–12™ is diluted in an intravenous fluid, the resulting solution is ready for immediate use. Use the prepared solution within 4 hours after dilution.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
- Handling of M.V.I-12 solution should be performed in a suitable work area, such as a laminar flow hood.

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2.4 Drug Incompatibilities

- M.V.I.–12™ (Multi-Vitamin Infusion without vitamin K) is not physically compatible with moderately alkaline solutions such as a sodium bicarbonate solution and other alkaline drugs such as acetazolamide sodium, aminophylline, ampicillin sodium, and chlorothiazide sodium.
- Folic acid is unstable in the presence of calcium salts such as calcium gluconate.
- Vitamin A and thiamine in M.V.I.–12™ may react with bisulfite solutions such as sodium bisulfite or vitamin K bisulfate. Patients should be monitored for vitamin A and thiamine deficiencies.
- Consult appropriate references for listings of physical and chemical compatibility of solutions and drugs with the vitamin infusion. In such circumstances, admixture or Y-site administration with vitamin solutions should be avoided.

3 DOSAGE FORMS AND STRENGTHS

M.V.I.–12™ Unit Vial is a sterile product in a two-chambered single-dose 10 mL vial which must be mixed just prior to use [*see Description (11)*].

4 CONTRAINDICATIONS

M.V.I.–12™ is contraindicated in patients who have a history of hypersensitivity to any of the vitamins in this product or existing hypervitaminosis due to any vitamins contained in this formulation.

5 WARNINGS AND PRECAUTIONS

5.1 Aluminum Toxicity

M.V.I.-12™ contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

5.2 Adherence of Vitamin A to Plastic

Studies have shown that vitamin A, which is found in M.V.I.-12™, may adhere to polyvinyl chloride (PVC) plastic, resulting in lower vitamin A concentrations in the administered M.V.I.-12™ doses. Therefore, blood vitamin concentrations should be periodically monitored and the administration of additional therapeutic doses of Vitamin A may be required [*see Warnings and Precautions (5.7)*].

5.3 Intravenous Fat Emulsions

Do not add M.V.I.–12™ directly to intravenous fat emulsions.

5.4 Allergic Reactions to Thiamine

Allergic reactions such as urticaria, periorbital and digital edema, have been reported following intravenous administration of thiamine, which is found in M.V.I.-12™. There have been rare reports of anaphylactoid reactions following large intravenous doses of thiamine. No fatal anaphylactoid reactions associated with M.V.I.–12™ have been reported.

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5.5 Hypervitaminosis A

Hypervitaminosis A, manifested by nausea, vomiting, headache, dizziness, blurred vision, has been reported in patients with renal failure receiving 1.5 mg/day retinol and in patients with liver disease. Therefore, supplementation of renal failure patients and patients with liver diseases with vitamin A, an ingredient found in M.V.I.-12™, should be undertaken with caution [*see Use in Specific Populations (8.6, 8.7)*].

5.6 Blood Sampling of Megaloblastic Anemia Patients

Do not administer M.V.I.–12™ to patients with suspected or diagnosed megaloblastic anemia prior to blood sampling for the detection of the folic acid and cyanocobalamin deficiencies. The folic acid and the cyanocobalamin in the M.V.I.–12™ solution can mask serum deficits of folic acid and cyanocobalamin in these patients.

5.7 Monitor Blood Vitamin Concentrations

In patients receiving parenteral multivitamins, such as with M.V.I.-12™, blood vitamin concentrations should be periodically monitored to determine if vitamin deficiencies or excesses are developing. M.V.I.–12™ may not correct long-standing specific vitamin deficiencies. The administration of additional therapeutic doses of specific vitamins may be required [*see Dosage and Administration (2.2)*].

5.8 Interference with Urine Glucose Testing

M.V.I-12™ contains Vitamin C, which is also known as ascorbic acid. Ascorbic acid in the urine may cause false negative urine glucose determinations.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling.

- Allergic and anaphylactoid reactions following intravenous administration of thiamine [*see Warnings and Precautions (5.4)*].
- Hypervitaminosis A [*see Warnings and Precautions (5.5)*].

Other adverse reactions:
Dermatologic: rash, erythema, pruritus
CNS: headache: dizziness, agitation, anxiety
Ophthalmic: diplopia

7 DRUG INTERACTIONS

A number of drug interactions between vitamins and other drugs have been reported. Consult appropriate references for additional specific vitamin-drug interactions. The following are examples of these types of interactions:

7.1 Clinical Interactions Affecting Drug Levels

Folic acid

Phenytoin metabolism may be increased by folic acid. Low serum concentration of phenytoin may result in increased seizure frequency.

Patient's response to methotrexate therapy may be decreased by folic acid.

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Pyridoxine

The metabolism of levodopa may be increased and its efficacy may be decreased by pyridoxine.

Antibiotics

Antibiotic activity of erythromycin, kanamycin, streptomycin, doxycycline, and lincomycin is decreased by thiamine, riboflavin, pyridoxine, niacinamide, and ascorbic acid. Bleomycin is inactivated *in vitro* by ascorbic acid and riboflavin.

7.2 Clinical Interactions Affecting Vitamin Levels

Hydralazine, Isoniazid

Pyridoxine requirements may be increased by concomitant administration of hydralazine or isoniazid.

Chloramphenicol

In patients with pernicious anemia, the hematologic response to vitamin B_{12} therapy may be inhibited by concomitant administration of chloramphenicol.

Phenytoin

Serum folic acid concentrations may be decreased by phenytoin and, therefore it should be avoided in pregnancy.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

M.V.I.-12™ has not been studied in pregnant women. Pregnant women should follow the U.S. Recommended Daily Allowances for their condition, because their vitamin requirements may be different than those of nonpregnant women.

8.3 Nursing Mothers

M.V.I.-12™ has not been studied in lactating women. Lactating women should follow the U.S. Recommended Daily Allowances for their condition, because their vitamin requirements may be different than a nonlactating women. Caution should be exercised when M.V.I.-12™ Unit Vial is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness of M.V.I.-12™ in children below the age of 11 years have not been established.

8.6 Patients with Renal Impairment

M.V.I.-12™ has not been studied in patients with renal impairment. Monitor renal function, calcium, phosphorus and vitamin A levels in patients with renal impairment [*see Warnings and Precautions (5.1, 5.5)*].

8.7 Patients with Liver Impairment

M.V.I.-12™ has not been studied in patients with liver impairment. Monitor vitamin A level in patients with liver disease, high alcohol consumption [*see Warnings and Precautions (5.5)*].

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10 OVERDOSAGE

There is no clinical experience with M.V.I.-12™ overdosage. Signs and symptoms of acute or chronic overdosage may be those of individual M.V.I.-12™ component toxicity.

11 DESCRIPTION

M.V.I.–12™ Unit Vial: A sterile product in a two-chambered single-dose Type I amber glass, vial, 10 mL, which must be mixed just prior to use.

LOWER CHAMBER OF UNIT VIAL*

Ingredient	Amount per Unit Dose
Fat Soluble Vitamins**	
Vitamin A (retinol)	1 mg (3,300 USP units)
Vitamin D (ergocalciferol)	5 mcg (200 USP units)
Vitamin E (dl-alpha-tocopheryl acetate)	10 mg (10 USP units)
Water Soluble Vitamins	
Vitamin C (ascorbic acid)	200 mg
Niacinamide	40 mg
Vitamin B_2 (as riboflavin 5-phosphate sodium)	3.6 mg
Vitamin B_1 (thiamine)	6 mg
Vitamin B_6 (pyridoxine HCl)	6 mg
Dexpanthenol (d-pantothenyl alcohol)	15 mg

* With 30% propylene glycol and 2% gentisic acid ethanolamide as stabilizers and preservatives; sodium hydroxide for pH adjustment; 1.6% polysorbate 80; 0.028% polysorbate 20; 0.002% butylated hydroxytoluene; 0.0005% butylated hydroxyanisole.

** Fat-soluble vitamins A, D, and E are water solubilized with polysorbate 80.

UPPER CHAMBER OF UNIT VIAL*

Biotin	60 mcg
Folic acid	600 mcg
Vitamin B_{12} (cyanocobalamin)	5 mcg

* With 30% propylene glycol and citric acid, sodium citrate, and sodium hydroxide for pH adjustment.

"Aqueous" multivitamin formula for intravenous infusion: M.V.I.–12™ (Multi-Vitamin Infusion without vitamin K) makes available a combination of important fat-soluble and water-soluble vitamins in an aqueous solution, formulated specially for incorporation into intravenous infusions. Through special processing techniques, the liposoluble vitamins A, D, and E have been solubilized in an aqueous medium with polysorbate 80, permitting intravenous administration of these vitamins.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity, mutagenicity and fertility studies were not performed.

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16 HOW SUPPLIED/STORAGE AND HANDLING

M.V.I. – 12™ UNIT VIAL NDC 61703-423-11 Boxes of 25 two-chambered 10 mL vials.

Minimize the exposure of M.V.I.–12™ to the light, because vitamins A, D and riboflavin are light sensitive.

Store at 2-8°C (36-46°F).

17 PATIENT COUNSELING INFORMATION

- Instruct patient that M.V.I.-12™ is indicated for the prevention of vitamin deficiency in patients on warfarin anticoagulant therapy receiving parenteral nutrition.
- M.V.I.–12™ is contraindicated in patients who have a history of hypersensitivity to any of the vitamins in this product or existing hypervitaminosis due to any vitamins contained in this formulation. Obtain detailed allergy and concomitant drug information from the patient, as well as if they have any kidney or liver disorders and if they are pregnant, prior to M.V.I.-12™ administration.
- Tell patients to watch for signs of allergic reactions such as urticaria, periorbital and digital edema, which have been reported following intravenous administration of thiamine.
- Instruct patients with renal impairment to immediately report signs of Hypervitaminosis A, manifested by nausea, vomiting, headache, dizziness, blurred vision, which has been reported in patients with renal failure receiving 1.5 mg/day retinol and in patients with liver disease.
- Instruct patients to report other adverse reactions such as rash, erythema, pruritus, headache, dizziness, agitation, anxiety, and diplopia.
- Explain the significance of periodic monitoring of blood vitamin concentrations to determine if vitamin deficiencies or excesses are developing. Monitor renal function, calcium, phosphorus, aluminum and vitamin A levels in patients with renal impairment.

EN-3087

Manufactured by
Hospira, Inc., Lake Forest, IL 60045 USA