M.V.I. ADULT- retinol, ergocalciferol, .alpha.-tocopherol acetate, dl-, phytonadione, ascorbic acid, niacinamide, riboflavin 5-phosphate sodium, thiamine hydrochloride, pyridoxine hydrochloride, dexpanthenol, biotin, folic acid, and cyanocobalamin Hospira, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use M.V.I. ADULT™ safely and effectively. See full prescribing information for M.V.I. ADULT. M.V.I. ADULT (multiple vitamins injection), for intravenous use Initial U.S. Approval: 2004
M.V.I. Adult is a combination of vitamins indicated for prevention of vitamin deficiency in adults and pediatric patients aged 11 years and above receiving parenteral nutrition (1)
DOSAGE AND ADMINISTRATION
 M.V.I. Adult is a combination product that contains the following vitamins: ascorbic acid, vitamin A, vitamin D, thiamine, riboflavin, pyridoxine, niacinamide, dexpanthenol, vitamin E, vitamin K, folic acid, biotin, and vitamin B₁₂ (2.1) Recommended daily dosage is 10 mL (2.2) Administer by intravenous infusion after dilution (2.1) Supplied as a single-dose and a pharmacy bulk package: <i>M.V.I. Adult Single Dose:</i> consists of two vials labeled Vial 1 and Vial 2. Transfer contents of Vial 1 to Vial 2. The mixed solution (10 mL) will provide a single 10 mL dose. Use within 4 hours of puncture (2.1, 2.3) <i>M.V.I.Adult Pharmacy Bulk Package:</i> consists of two vials labeled Vial 1 and Vial 2. Transfer the contents of Vial
1 to Vial 2. The mixed solution (100 mL) will provide ten 10 mL single doses to patients in a pharmacy admixture program. Use within 4 hours of puncture (2.1, 2.3)
• Prior to intravenous administration, dilute the once daily dose of 10 mL by adding to at least 500 to 1,000 mL
 intravenous parenteral nutrition solution containing dextrose or saline (2.3) After dilution in an intravenous infusion, refrigerate resulting solution unless used immediately. Use solution within 24 hours after dilution (2.3) Monitor blood vitamin concentrations (2.4)
 See Full Prescribing Information for drug incompatibilities (2.5)
DOSAGE FORMS AND STRENGTHS
• Injection (3):
 Single dose: consists of two vials labeled Vial 1 (5 mL) and Vial 2 (5 mL) Pharmacy bulk package: consists of two vials labeled Vial 1 (50 mL) and Vial 2 (50 mL)
• See Full Prescribing Information for vitamin strengths (3, 11)
CONTRAINDICATIONS
 Hypersensitivity to any of the vitamins or excipients (4) Existing hypervitaminosis (4)
WARNINGS AND PRECAUTIONS
 Decreased Anticoagulant Effect of Warfarin: Periodically monitor prothrombin time/INR. (5.1) Risk of Aluminum Toxicity: For at risk patients (renal failure or those with prolonged therapy), periodically monitor aluminum levels with prolonged administration (5.2) Low Vitamin A levels: Monitor vitamin A levels (5.3) Allergic Reactions: to thiamine may occur (5.4)
 Hypervitaminosis A: Patients with renal failure or liver disease may be at higher risk (5.5) Interference with Manalah Jatrin Anomia Discussion Anomia during testing for this discussion (5.6)

• Interferes with Megaloblastic Anemia Diagnosis: Avoid use during testing for this disorder (5.6)

- *Risk of Vitamin Deficiencies or Excess:* Monitor blood vitamin concentrations (5.7)
- *False Negative Urine Glucose Tests:* May occur due to vitamin C (5.8)

Adverse reactions have included anaphylaxis, rash, erythema, pruritus, headache, dizziness, agitation, anxiety, diplopia (6) 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.

- *Phenytoin:* Folic acid may decrease phenytoin blood levels and increase the risk of seizure activity (7.1)
- *Methotrexate:* Folic acid may decrease response to methotrexate (7.1)
- *Levodopa:* Pyridoxine may decrease blood levels of levodopa and levodopa efficacy may decrease (7.1)
- *Antibiotics:* Thiamine, riboflavin, pyridoxine, niacinamide, and ascorbic acid decrease activities of erythromycin, kanamycin, streptomycin, doxycycline, and lincomycin (7.1)
- *Bleomycin:* Ascorbic acid and riboflavin may reduce the activity of bleomycin (7.1)

Effects of other drugs on M.V.I. Adult:

- *Hydralazine, Isoniazid:* Concomitant administration of hydralazine or isoniazid may increase pyridoxine requirements (7.2)
- *Chloramphenicol:* In patients with pernicious anemia, hematologic response to vitamin B₁₂ may be inhibited by concomitant administration of chloramphenicol (7.2)
- *Phenytoin:* May decrease folic acid concentrations (7.2)

- *Pregnant and Nursing Mothers*: Pregnant and nursing women should follow the U.S. Recommended Daily Allowances for their condition, because their vitamin requirements may exceed those of nonpregnant and nonlactating women (8.1, 8.3)
- *Pediatric Use*: Safety and effectiveness in pediatric patients below the age of 11 years have not been established (8.4)
- *Renal Impairment:* Monitor renal function, calcium, phosphorus and vitamin A levels (8.6)
- *Hepatic Impairment:* Monitor vitamin A levels (8.7)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 11/2017

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

- 2.1 Important Dosage and Administration Instructions
- 2.2 Dosage Information
- 2.3 Preparation and Administration Instructions
- 2.4 Monitoring Vitamin Blood Levels
- 2.5 Drug Incompatibilities

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

- 5.1 Decreased Anticoagulant Effect of Warfarin
- 5.2 Aluminum Toxicity
- 5.3 Risk of Low Vitamin A Levels
- 5.4 Allergic Reactions to Thiamine
- 5.5 Hypervitaminosis A
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5.7 Potential to Develop Vitamin Deficiencies or Excesses 5.8 Interference with Urine Glucose Testing 6 ADVERSE REACTIONS **7 DRUG INTERACTIONS** 7.1 Effect of M.V.I. Adult on Other Drugs 7.2 Effect of Other Drugs on M.V.I. Adult **8 USE IN SPECIFIC POPULATIONS** 8.1 Pregnancy **8.3** Nursing Mothers 8.4 Pediatric Use 8.5 Geriatric Use 8.6 Renal Impairment 8.7 Hepatic 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.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

M.V.I. Adult[™] is a combination of vitamins indicated for the prevention of vitamin deficiency in adults and pediatric patients aged 11 and older receiving parenteral nutrition.

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

2 DOSAGE AND ADMINISTRATION

2.1 Important Dosage and Administration Instructions

M.V.I. Adult is a combination product that contains the following vitamins: ascorbic acid, vitamin A, vitamin D, thiamine, riboflavin, pyridoxine, niacinamide, dexpanthenol, vitamin E, vitamin K, folic acid, biotin, and vitamin B₁₂.

M.V.I. Adult is supplied as a single dose or as a pharmacy bulk package for intravenous use intended for administration by intravenous infusion after dilution:

- <u>M.V.I. Adult Single Dose</u>: consists of two vials which must be mixed prior to use. The mixed solution will provide a single 10 mL dose which must be diluted prior to intravenous administration [*see Dosage and Administration (2.3)*].
- <u>M.V.I. Adult Pharmacy Bulk Package</u>: consists of two pharmacy bulk vials which must be mixed prior to use. The mixed solution will provide ten 10 mL single doses which must be diluted prior to intravenous administration. Pharmacy bulk package of M.V.I. Adult is intended for dispensing of single doses to multiple patients in a pharmacy admixture program and is restricted to the preparation of admixtures for infusion [*see Dosage and Administration (2.3)*].

Do not administer M.V.I. Adult as a direct, undiluted intravenous injection as it may cause dizziness, faintness, and tissue irritation.

2.2 Dosage Information

The recommended daily dosage volume is 10 mL. One daily dose (10 mL) is diluted by adding directly to a specified volume of an intravenous fluid [*see Dosage and Administration (2.3)*].

Patients with multiple vitamin deficiencies or with increased vitamin requirements may need multiple daily dosages as indicated or additional doses of individual vitamins.

2.3 Preparation and Administration Instructions

M.V.I. Adult supplied as a single dose:

- M.V.I Adult is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).
- Transfer the contents of Vial 1 (5 mL of solution) into the contents of Vial 2 (5 mL of solution). The mixed solution (10 mL) will provide a single 10 mL dose.
- Once the closure system has been penetrated, complete withdrawal of vial contents within 4 hours. Mixed solution may be stored for up to 4 hours refrigerated.
- Visually inspect for particulate matter and discoloration prior to intravenous administration.
- Utilizing a suitable sterile automated compounding device or dispensing pin for accuracy, aseptically transfer the 10 mL dose into a plastic or glass bottle containing at least 500 to 1,000 mL intravenous parenteral nutrition solution containing dextrose or saline.
- After M.V.I. Adult is diluted in an intravenous infusion, refrigerate the resulting solution unless it is to be used immediately, and use the solution within 24 hours after dilution.
- Minimize exposure to light because some of the vitamins in M.V.I. Adult, particularly A, D and riboflavin, are light sensitive.

M.V.I. Adult supplied as a pharmacy bulk package:

- M.V.I. Adult is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).
- Transfer the contents of Vial 1 (50 mL) into Vial 2 (50 mL). The mixed solution (100 mL) will provide ten 10 mL single doses to patients in a pharmacy admixture program.
- Each bulk vial closure shall be penetrated only one time with a suitable sterile transfer device or dispensing set that allows measured dispensing of the contents.
- Once the closure system has been penetrated, complete dispensing from the pharmacy bulk vial within 4 hours. Mixed solution may be stored for up to 4 hours refrigerated.
- Discard unused portion.
- Visually inspect for particulate matter and discoloration prior to administration.
- Utilizing a suitable sterile automated compounding device or dispensing pin for accuracy, aseptically transfer each 10 mL dose into a plastic or glass bottle containing at least 500 to 1,000 mL intravenous parenteral nutrition solution containing dextrose or saline.
- After M.V.I. Adult is diluted in an intravenous infusion, refrigerate the resulting solution unless it is to be used immediately, and use the solution within 24 hours after dilution.
- Minimize exposure to light because some of the vitamins in M.V.I. Adult, particularly A, D and riboflavin, are light sensitive.

2.4 Monitoring Vitamin Blood Levels

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.

2.5 Drug Incompatibilities

- M.V.I. Adult 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.Adult may react with bisulfite solutions such as sodium bisulfite or vitamin K bisulfite. Do not add M.V.I. Adult directly to intravenous fat emulsions.
- Consult appropriate references for listings of physical and chemical compatibility of solutions and drugs with M.V.I. Adult. In such circumstances, admixture or Y-site administration with M.V.I. Adult should be avoided.

3 DOSAGE FORMS AND STRENGTHS

M.V.I. Adult is an injection available as a:

- Single dose: consisting of two vials labeled Vial 1 and Vial 2. Vial 1 is an amber vial containing a clear, amber to orange colored solution. Vial 2 is an amber vial containing a clear to light straw colored solution. Both vials must be mixed prior to use. The mixed solution (10 mL) will provide a single 10 mL dose [*see Dosage and Administration (2.3) and Description (11)*].
- Pharmacy bulk package: consisting of two vials labeled Vial 1 and Vial 2. Vial 1 is an amber vial containing a clear, amber to orange colored solution. Vial 2 is an amber vial containing a clear to light straw colored solution. Both vials must be mixed prior to use. The mixed solution (100 mL) will provide ten 10 mL single doses [*see Dosage and Administration (2.3)*].

See Description section for vitamin strengths [see Description (11)].

4 CONTRAINDICATIONS

M.V.I. Adult is contraindicated in patients who have:

- A history of known hypersensitivity to any of the vitamins or excipients in M.V.I. Adult [see *Warnings and Precautions (5.4), Adverse Reactions (6)*]
- An existing hypervitaminosis

5 WARNINGS AND PRECAUTIONS

5.1 Decreased Anticoagulant Effect of Warfarin

M.V.I. Adult contains Vitamin K which may decrease the anticoagulant effect of warfarin. In patients who are on warfarin anticoagulant therapy receiving M.V.I. Adult, prothrombin time/INR should be periodically monitored to determine if the dose of warfarin needs to be adjusted.

5.2 Aluminum Toxicity

M.V.I. Adult contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration in patients with renal impairment. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Patients with impaired kidney function, including premature neonates, who receive parenteral levels of

aluminum at greater than 4 to 5 micrograms per kg per day, accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration. To prevent aluminum toxicity monitor periodically aluminum levels with prolonged parenteral administration of M.V.I. Adult.

5.3 Risk of Low Vitamin A Levels

Vitamin A may adhere to plastic, resulting in lower vitamin A concentrations after administration of M.V.I. Adult. Therefore, blood vitamin concentrations should be periodically monitored and the administration of additional therapeutic doses of Vitamin A may be required.

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. Adult. There have been rare reports of anaphylaxis following intravenous doses of thiamine. No fatal anaphylaxis reactions associated with M.V.I. Adult have been reported.

5.5 Hypervitaminos is 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. Adult, should be undertaken with caution [*see Use in Specific Populations (8.6, 8.7)*]. Blood levels of Vitamin A should be monitored periodically.

5.6 Interference with Diagnosis of Megaloblastic Anemia

M.V.I. Adult contains folic acid and cyanocobalamin which can mask serum deficits of folic acid and cyanocobalamin in patients with megaloblastic anemia. Avoid the use of M.V.I. Adult in patients with suspected or diagnosed megaloblastic anemia prior to blood sampling for the detection of the folic acid and cyanocobalamin deficiencies.

5.7 Potential to Develop Vitamin Deficiencies or Excesses

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

5.8 Interference with Urine Glucose Testing

M.V.I. Adult 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 section of the labeling.

- Allergic Reactions to Thiamine [see Warnings and Precautions (5.4)].
- Hypervitaminosis A [see Warnings and Precautions (5.5)].

The following adverse reactions have been identified during post approval use of M.V.I. Adult. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Dermatologic: rash, erythema, pruritus *CNS*: headache, dizziness, agitation, anxiety

7 DRUG INTERACTIONS

7.1 Effect of M.V.I. Adult on Other Drugs

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<u>Phenytoin:</u> Folic acid may increase phenytoin metabolism and lower the serum concentration of phenytoin resulting in increased seizure activity.

<u>Methotrexate:</u> Folic acid may decrease a patient's response to methotrexate therapy.

<u>Levodopa</u>: Pyridoxine may increase the metabolism of levodopa (decrease blood level of levodopa) and decrease its efficacy.

<u>Antibiotics</u>: Thiamine, riboflavin, pyridoxine, niacinamide, and ascorbic acid decrease antibiotic activities of erythromycin, kanamycin, streptomycin, doxycycline, and lincomycin.

<u>Bleomycin</u>: Ascorbic acid and riboflavin inactivate bleomycin *in vitro*, thus the activity of bleomycin may be reduced.

7.2 Effect of Other Drugs on M.V.I. Adult

Hydralazine or Isoniazid:

Concomitant administration of hydralazine or isoniazid may increase pyridoxine requirements.

Chloramphenicol:

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

<u>Phenytoin:</u>

Phenytoin may decrease serum folic acid concentrations.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

M.V.I. Adult has not been studied in pregnant women. Pregnant women should follow the U.S. recommended daily allowances for pregnancy because their vitamin requirements may exceed those of nonpregnant women. Animal reproduction studies have not been conducted with M.V.I. Adult (multiple vitamins injection) administered by intravenous infusion.

8.3 Nursing Mothers

M.V.I. Adult 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 exceed those of nonlactating women. Caution should be exercised when M.V.I. Adult is administered to a nursing woman.

8.4 Pediatric Use

M.V.I. Adult is indicated for the prevention of vitamin deficiency in pediatric patients aged 11 years and older receiving parenteral nutrition. M.V.I. Adult is not indicated for use in pediatric patients below the age of 11 years.

8.5 Geriatric Use

Reported clinical experience has not identified differences in responses between the elderly and

younger patients.

8.6 Renal Impairment

M.V.I. Adult 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* (5.2, 5.5)].

8.7 Hepatic Impairment

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

10 OVERDOSAGE

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

11 DESCRIPTION

M.V.I. Adult (multiple vitamins injection) is a sterile product consisting of two vials provided as a single dose or as a pharmacy bulk package for intravenous use intended for administration by intravenous infusion after dilution.

Table 1 provides the strengths of the vitamins provided in vial 1 and vial 2:

Vial 1*	
Fat Soluble Vita	mins**
Ingredient	Amount per Unit Dose
Vitamin A (retinol)	1 mg ^a
Vitamin D (ergocalciferol)	5 mcg ^b
Vitamin E (dl-alpha-tocopheryl acetate)	10 mg ^c
Vitamin K (phytonadione)	150 mcg
Water Soluble V	litamins
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

Table 1: M.V.I. ADULT FORMULATION (INTENDED FOR AGES 11 AND OLDER)

* 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, E and K are water solubilized with polysorbate 80.

(a) 1 mg vitamin A equals 3,300 USP units.

(b) 5 mcg ergocalciferol equals 200 USP units.

(c) 10 mg vitamin E equals 10 USP units.

V	ial 2*
Biotin	60 mcg
Folic acid	600 mcg
B ₁₂ (cyanocobalamin)	5 mcg

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

Multiple vitamin preparation for intravenous infusion:

M.V.I. Adult (multiple vitamins injection) makes available a combination of fat-soluble and watersoluble vitamins in an aqueous solution, formulated for incorporation into intravenous infusions. The liposoluble vitamins A, D, E, and K 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.

16 HOW SUPPLIED/STORAGE AND HANDLING

M.V.I. ADULT is an injection supplied in the following package configurations:

M.V.I. ADULT Single-Dose

		Each	Each
Unit of Sale	Each Box	Vial 1	Vial 2
NDC 61703-434-82	NDC 61703-434-01	NDC 61703-426-02	NDC 61703-430-02
Bundle of 10 Boxes of	Box of 2 vials	10 Vitamin Blend,	3 Vitamin Blend,
2 vials (Vial 1 and	(Vial 1 and Vial 2)	5 mL	5 mL
Vial 2)			

Vial 1 is an amber vial containing a clear, amber to orange colored solution. Vial 2 is an amber vial containing a clear to light straw colored solution. Mix contents of Vial 1 and Vial 2 to provide a single 10 mL dose [see Dosage and Administration (2.3)].

M.V.I. ADULT Pharmacy Bulk Package

	Intermediate	Each	Each
Unit of Sale	Multi-Pack	Vial 1	Vial 2
NDC 61703-422-83	NDC 61703-422-78	NDC 61703-426-01	NDC 61703-430-01
Case of 2 Boxes of	Box of 10 vials	10 Vitamin Blend,	3 Vitamin Blend,
10 vials (5 Vial 1 and	(5 Vial 1 and 5 Vial 2)	50 mL	50 mL
5 Vial 2)			

Vial 1 is an amber vial containing a clear, amber to orange colored solution. Vial 2 is an amber vial containing a clear to light straw colored solution. Mix contents of Vial 1 and Vial 2 to provide ten 10 mL single doses [see Dosage and Administration (2.3)].

See Description section for vitamin strengths [see Description (11)].

Minimize the exposure of M.V.I. Adult to light, because vitamins A, D and riboflavin are light sensitive. Store at 2-8°C (36-46°F).

17 PATIENT COUNSELING INFORMATION

Instruct patients (if age appropriate) and caregivers:

- To watch for and immediately report signs of allergic reactions (i.e. urticaria, periorbital and digital edema).
- To watch for and immediately report signs of hypervitaminosis A, manifested by nausea, vomiting, headache, dizziness, blurred vision, if patients have renal impairment.
- To report other adverse reactions such as rash, erythema, pruritus, headache, dizziness, agitation, anxiety, and diplopia.
- That patients on warfarin anticoagulant therapy will be monitored periodically for blood prothrombin/ INR levels to determine if the dose of warfarin needs to be adjusted.
- About the significance of periodic monitoring of blood vitamin concentrations to determine if vitamin deficiencies or excesses are developing .
- About the need to monitor renal function, calcium, phosphorus, aluminum, and vitamin A levels in patients with renal impairment.



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

LAB-0989-2.0

PRINCIPAL DISPLAY PANEL - Kit Carton - NDC 61703-422-78

Sterile Contents: 10 vials, 50 mL Fill each (5 Vial 1 and 5 Vial 2) Mix contents of Vial 1 with Vial 2 to provide 10 single doses.

NDC 61703-422-78

Rx only

M.V.I. ADULTTM (multiple vitamins injection)

PHARMACY BULK PACKAGE. NOT FOR DIRECT INFUSION.

See insert for important information on pharmacy bulk package.

Store under refrigeration, 2 - 8°C (36 - 46°F). Store Upright.

Hospira

Sterile Contents: 10 vials, 50 mL Fill each (5 Vial 1 and 5 Vial 2) Mix contents of Vial 1 with Vial 2 to provide 10 single doses.

M.V.I. ADULTTM (multiple vitamins injection)

NDC 61703-422-78 Rx only



PHARMACY BULK PACKAGE. NOT FOR DIRECT INFUSION.

See insert for important information on pharmacy bulk package. Store under refrigeration, 2 - 8°C (36 - 46°F). Store Upright.







Store under refrigeration, 2 - 8°C (36 - 46°F). Store Upright. See insert for important information on pharmacy bulk package.

PHARMACY BULK PACKAGE. NOT FOR DIRECT IN FUSION.

(noitosini snimstiv slqitlum)

Mix contents of Vial 2 to provide 10 single doses. (S leiv & bner leiv &) Contents: 10 vials, 50 mL Fill each **JIGNIE**

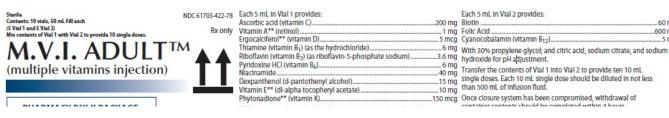
.60 mca

..600 mcg

.... 5 mcg

Rx only

NDC 61703-422-78



PHARMACY BULK PACKAG	Ε.
NOT FOR DIRECT INFUSION	

See Insert for Important Information on pharmacy bulk package. Store under refrigeration, 2 - 8°C (36 - 46°F). Store Upright. 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, E and K are water solubilized with polysorbate 80.

CA-5953

container contents should be completed within 4 hours. DISCARD UNUSED PORTION. Consult package Insert for dosage and full prescribing information



M.V.		NDC 61703-422-78 Rx only
	ACY BULK PACKAGE. R DIRECT INFUSION. See Insert for Important Information	on
	pharmacy bulk package. Store under refrigeration, 2 - 8°C (36 - 46°F). Store Upright.	Hospira

PRINCIPAL DISPLAY PANEL - 50 mL Vial Label - NDC 61703-426-01

Hospira, Inc., Lake Forest, IL 60045 USA

M.V.I. ADULT™ (multiple vitamins injection)

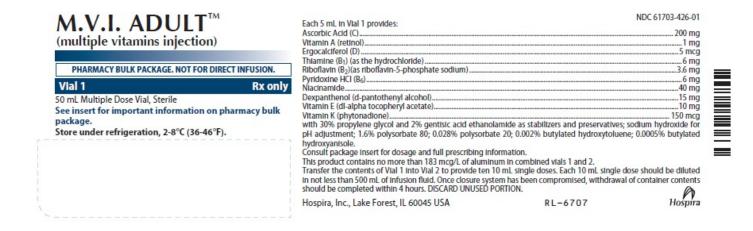
PHARMACY BULK PACKAGE. NOT FOR DIRECT INFUSION.

Vial 1 Rx only

50 mL Multiple Dose Vial, Sterile

See insert for important information on pharmacy bulk package.

Store under refrigeration, 2-8°C (36-46°F).



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NDC 61703-430-01

M.V.I.-ADULT[™] (multiple vitamins injection)

PHARMACY BULK PACKAGE. NOT FOR DIRECT INFUSION.

Vial 2 Rx only

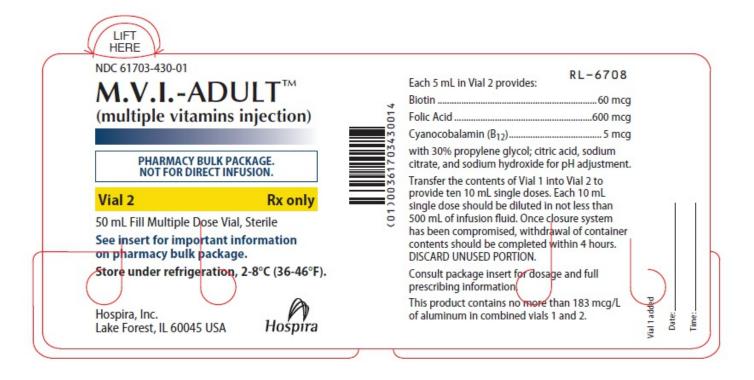
50 mL Fill Multiple Dose Vial, Sterile

See insert for important information on pharmacy bulk package.

Store under refrigeration, 2-8°C (36-46°F).

Hospira, Inc. Lake Forest, IL 60045 USA

Hospira



PRINCIPAL DISPLAY PANEL - Kit Carton - NDC 61703-434-01

Sterile

NDC 61703-434-01 Rx only

M.V.I. ADULT[™] (multiple vitamins injection)

FOR DILUTION IN INTRAVENOUS INFUSIONS ONLY.

Contents: Vial 1 (5 mL) and Vial 2 (5 mL). Both vials to be used for a single dose. Store under refrigeration, 2 - 8°C (36 - 46°F). Store Upright Hospira



CA-6053

Sterile

NDC 61703-434-01 Rx only

Hospira

M.V.I. ADULTTM (multiple vitamins injection)

FOR DILUTION IN INTRAVENOUS INFUSIONS ONLY.

Contents: Vial 1 (5 mL) and Vial 2 (5 mL). Both vials to be used for a single dose. Store under refrigeration, 2 - 8°C (36 - 46°F). Store Upright



The contents of both vials should be added to not less than 500 mL of infusion fluid.

Each vial contains a sufficient amount to permit withdrawal and administration of 5 mL.

Usual dosage: See insert.

Oil-soluble vitamins A, D, E, and K in Vial 1 water solubilized with 1.6% polysorbate 80.

Hospira, Inc. Lake Forest, IL 60045 USA

PRINCIPAL DISPLAY PANEL - 5 mL Vial Label - NDC 61703-426-02

M.V.I. ADULT[™] (multiple vitamins injection)

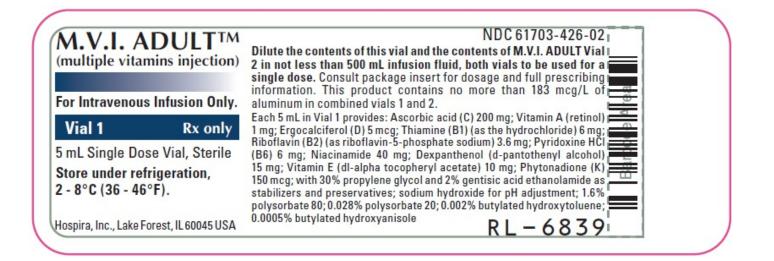
For Intravenous Infusion Only.

Vial 1 Rx only

5 mL Single Dose Vial, Sterile

Store under refrigeration, 2 - 8°C (36 - 46°F).

Hospira, Inc., Lake Forest, IL 60045 USA



PRINCIPAL DISPLAY PANEL - 5 mL Vial Label - NDC 61703-430-02

NDC 61703-430-02

M.V.I. ADULT[™] (multiple vitamins injection)

For Intravenous Infusion Only.

Vial 2 Rx only

5 mL Single Dose Vial, Sterile

Store under refrigeration, 2 - 8°C (36 - 46°F).

Hospira, Inc., Lake Forest, IL 60045 USA

onsult package insert for d d full prescribing informati s product contains no mo 8 mcg/L of aluminum in co ls 1 and 2.	NDC 61703-430-02 M.V.I. ADULT TM (multiple vitamins injection) For Intravenous Infusion Only. Vial 2 Rx only 5 mL Single Dose Vial, Sterile Store under refrigeration, 2 - 8°C (36 - 46°F). Hospira, Inc., Lake Forest, IL 60045 USA	Dilute the contents of this vial and the contents of M.V.I. ADULT Vial 1 in not less than 500 mL infusion fluid, both vials to be used for a single dose. Each 5 mL in Vial 2 provides: Biotin 60 mcg; Folic Acid 600 mcg; Cyanocobalamin (B12) 5 mcg with 30% propylene glycol; and sodium hydroxide for pH adjustment. RL-6 840	
C PF 6.2	Hospira, Inc., Lake Forest, IL 60045 USA		

M.V.I. ADULT

retinol, ergocalciferol, .alpha.-tocopherol acetate, dl-, phytonadione, ascorbic acid, niacinamide, riboflavin 5phosphate sodium, thiamine hydrochloride, pyridoxine hydrochloride, dexpanthenol, biotin, folic acid, and cyanocobalamin kit

	Packaging Item Code NDC:61703-422-83			nem Code (Source)	NDC:01/0	-42Z
Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:61703-422-83 2 in 1 CASE 01/27/2015 01/27/2015 1 NDC:61703-422-78 5 in 1 BOX 01/27/2015 01/27/2015 Quantity of Parts In 1 KIT 01/27/2015 01/27/2015 01/27/2015 Quantity of Parts Package Quantity Total Product Quantity 01/27/2015 Part 1 1 VIAL, MULTI-DOSE 50 mL 01/27/2015 Part 2 1 VIAL, MULTI-DOSE 50 mL 01/27/2015 Part 1 of 2 Start Date Start Date 01/27/2015 Part 1 of 2 Start Date Start Date Start Date Part 1 of 2 Start Date Start Date Start Date Part 2 1 VIAL, MULTI-DOSE 50 mL Start Date Start Date Part 1 of 2 Start Date Start Date Start Date Start Date Part 2 1 VIAL, MULTI-DOSE Start Date Start Date Start Date Part 1 of 2 Start Date Start Date Start Date Start Date Part 2 Start Date Start	Item Code NDC:61703-422-83	Package Desc	intian D			
Item Code Package Description Marketing Start Date Marketing End Date 1 DDC:61703-422-83 2 in 1 CASE 01/27/2015 0 1 DDC:61703-422-78 5 in 1 BOX 0 0 0 1 DDC:61703-422-78 5 in 1 BOX 0 0 0 0 Quantity of Parts Fackage Quantity Total Product Quantity 0	Item Code NDC:61703-422-83	Package Desc	vintion N			
1 NDC:6 1703-422-83 2 in 1 CASE 0 1/27/2015 0 1 NDC:6 1703-422-78 5 in 1 BOX 0 0 0 1 NDC:6 1703-422-78 5 in 1 BOX 0 0 0 0 Quantity of Parts Part # Package Quantity Total Product Quantity Part 1 1 VIAL, MULTI-DOSE 50 mL Part 1 of 2 RETINOL, ERGOCALCIFEROL, ALPHATOCOPHEROL ACETATE, DL-, PHYTONADIONE, ASCORBIC ACID, NIACINAMIDE, RIBOFLAVIN 5-PHOSPHATE SODIUM, THIAMINE HYDROCHLORIDE, PYRIDOXINE HYDROCHLORIDE, AND DEXPANTHENOL Pretuoi (fero), .alphatocopherol acetate, dl-, phytonadione, ascorbic acid, niacinamide, riboflavin 5 phosphate sodium, thiamine hydrochloride, pyridoxine hydrochloride, and dexpanthenol injection, solution, concentrate Product Information INTRAVENOUS Active Ingredient/Active Moiety	NDC:61703-422-83	Package Desc	vintion N			
1 NDC:61703-422-78 5 in 1 BOX Im 1 KIT 1 1 in 1 KIT Im 1 KIT Im 1 KIT Quantity of Parts Part # Package Quantity Total Product Quantity Part # Package Quantity So mL Part 1 1 VIAL, MULTI-DOSE 50 mL Part 1 of 2 RETINOL, ERGOCALCIFEROL, ALPHATOCOPHEROL ACETATE, DL-, PHYTONADIONE, ASCORBIC ACID, NIACINAMIDE, RIBOFLAVIN 5-PHOSPHATE SODIUM, THIAMINE HYDROCHLORIDE, PYRIDOXINE HYDROCHLORIDE, AND DEXPANTHENOL retinol, ergocalciferol, alphatocopherol acetate, dl-, phytonadione, ascorbic acid, niacinamide, riboflavin 5 phosphate sodium, thiamine hydrochloride, pyridoxine hydrochloride, and dexpanthenol injection, solution, concentrate Product Information MIRAVENOUS Active Ingredient/Active Moiety			ription w	larketing Start Date	Marketing E	nd Date
I in 1 KTT	NDC:61703-422-78	2 in 1 CASE	0 1/27/	20 15		
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Part # Package Quantity Total Product Quantity Part 1 1 VIAL, MULTHOSE 50 mL Part 2 1 VIAL, MULTHOSE 50 mL Part 1 of 2 RETINOL, ERGOCALCIFEROL, ALPHATOCOPHEROL ACETATE, DL-, PHYTONADIONE, ASCORBIC ACID, NIACINAMIDE, RIBOFLAVIN 5-PHATE SODIUM, THIAMINE HYDROCHLORIDE, PYRIDOXINE HYDROCHLORIDE, AND DEXPANTHENOL Protochloride, and bexpenthenol injection, solution, concentrate Product Information Ingredient/Active Moiety Adtive Ingredient/Active Moiety		1 in 1 KIT				
Part # Package Quantity Total Product Quantity Part 1 1 VIAL, MULTHOSE 50 mL Part 2 1 VIAL, MULTHOSE 50 mL Part 1 of 2 RETINOL, ERGOCALCIFEROL, ALPHATOCOPHEROL ACETATE, DL-, PHYTONADIONE, ASCORBIC ACID, NIACINAMIDE, RIBOFLAVIN 5-PHATE SODIUM, THIAMINE HYDROCHLORIDE, PYRIDOXINE HYDROCHLORIDE, AND DEXPANTHENOL retinol, ergocalciferol, alphatocopherol acetate, dl-, phytonadione, ascorbic acid, niacinamide, riboflavin 5 phosphate sodium, thiamine hydrochloride, pyridoxine hydrochloride, and dexpanthenol injection, solution, concentrate Product Information Ingredient/Active Moiety Ingredient Name Basis of Strength Stre						
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Part 2 1 VIAL, MULTI-DOSE 50 mL Part 1 of 2 RETINOL, ERGOCALCIFEROL, ALPHATOCOPHEROL ACETATE, DL-, PHYTONADIONE, ASCORBIC ACID, NIACINAMIDE, RIBOFLAVIN 5-PHOSPHATE SODIUM, THIAMINE HYDROCHLORIDE, PYRIDOXINE HYDROCHLORIDE, AND DEXPANTHENOL retinol, ergocalciferol, alphatocopherol acetate, dl-, phytonadione, ascorbic acid, niacinamide, riboflavin 5 phosphate sodium, thiamine hydrochloride, pyridoxine hydrochloride, and dexpanthenol injection, solution, solution, concentrate Product Information Item Code (Source) NDC:61703-426 Route of Administration NTRAVENOUS Kative Ingredient/Active Mojety Ingredient Name So mL	'art# P	ackage Quantity		Total Produ	ict Quantity	
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RETINOL, ERGOCALCIFEROL, .ALPHATOCOPHEROL ACETATE, DL-, PHYTONADIONE, ASCORBIC ACID, NIACINAMIDE, RIBOFLAVIN 5- PHOSPHATE SODIUM, THIAMINE HYDROCHLORIDE, PYRIDOXINE HYDROCHLORIDE, AND DEXPANTHENOL retinol, ergocalciferol, .alphatocopherol acetate, dl-, phytonadione, ascorbic acid, niacinamide, riboflavin 5 phosphate sodium, thiamine hydrochloride, pyridoxine hydrochloride, and dexpanthenol injection, solution, concentrate Product Information Item Code (Source) NDC:61703-426 Route of Administration NTRAVENOUS	art 2 1 VIAL, MULTI-D	OSE	50 mL			
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PHYTONADIONE, ASCORBIC ACID, NIACINAMIDE, RIBOFLAVIN 5- PHOSPHATE SODIUM, THIAMINE HYDROCHLORIDE, PYRIDOXINE HYDROCHLORIDE, AND DEXPANTHENOL retinol, ergocalciferol, .alphato-copherol acetate, dl-, phytonadione, ascorbic acid, niacinamide, riboflavin 5 chosphate sodium, thiamine hydrochloride, pyridoxine hydrochloride, and dexpathenol injection, solution, concentrate Product Information ktem Code (Source) NDC:61703-426 Route of Administration INTRAVENOUS						
Item Code (Source) NDC:61703-426 Route of Administration INTRAVENOUS Active Ingredient/Active Moistration Stream of the strength of the strengt of the strength of the strength of the strengt	etinol, ergocalciferol bhosphate sodium, thi	, .alphatocopherol a	cetate, dl-, phyto	nadione, ascorbic acid,		
Item Code (Source) NDC:61703-426 Route of Administration INTRAVENOUS Active Ingredient/Active Moissuration Stream of the strength of the strengt of the strength of the strength of the streng	Duoduot Informatic					
Route of Administration INTRAVENOUS Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength			426			
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Ingredient Name Basis of Strength Stre	Route of Administration	on INTRAVEN	IOUS			
Ingredient Name Basis of Strength Stre						
	Active Ingredient/#	Active Moiety				
	0	5	lame	В	asis of Strength	Strengt
RELINGL (UNIT GZSHUXKKYT) (RELINGL - UNIT GZSHUXKKYT) RELINGL (RELINGL)			2SH0XKK91)	RET	INOL	
ERGOCALCIFEROL (UNII: VS041H42XC) (ERGOCALCIFEROL - UNII: VS041H42XC) ERGOCALCIFEROL 5 ug in	ETINOL (UNII: G2SH0X	KK91) (RETINOL - UNII:C				1 mg in 5 mL
ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHATOCOPHEROL, DL- UNII:7QWA1RIO01) .ALPHATOCOPHEROL, DL- UNII:7QWA1RIO01	``		,	VS041H42XC) ERC	GOCALCIFEROL	0
PHYTONADIONE (UNII: A034SE7857) (PHYTONADIONE - UNII: A034SE7857) PHYTONADIONE 150 ug	ERGOCALCIFEROL (UN ALPHATOCOPHEROI	NII: VS041H42XC) (ERGO	CALCIFEROL - UNII:	HATOCOPHEROL, .AL		in 5 mL 5 ug in 5 n
	ERGOCALCIFEROL (UN ALPHATOCOPHEROI DL UNII:7QWA1RIO01)	NII: VS041H42XC) (ERGO(2 ACETATE, DL- (UNII: W	CALCIFEROL - UNII: /R1WPI7EW8) (.ALPI	IATOCOPHEROL, .ALI DL-	PHATOCOPHEROL,	in 5 mL 5 ug in 5 m 10 mg
ASUUKBIL AUTUTUNT PUNUKAPUUKITASUUKBIL AUTU-TUNTPUNUKAPUUKI $ASUUKBIL AUTU$	ERGOCALCIFEROL (UN ALPHATOCOPHEROI DL UNII:7QWA1RIO01) PHYTONADIONE (UNII:	NII: VS041H42XC) (ERGO L ACETATE, DL- (UNII: W A034SE7857) (PHYTONA	CALCIFEROL - UNII: R1WPI7EW8) (.ALPI DIONE - UNII:A034S	HATOCOPHEROL, ALL DL- E7857) PHY	PHATOCOPHEROL, TONADIONE	in 5 mL 5 ug in 5 r 10 mg in 5 mL 150 ug

RIBOFLAVIN 5'-PHOSPHATE SODIUM (UNII: 20 RD1DZH99) (FLAVIN MONONUCLEOTIDE - UNII:7N464URE7E)

in 5 mL

3.6 mg

FLAVIN

MONONUCLEOTIDE

						in 5 mL
PYRIDO XINE HYDF	RO CHLO RIDE (UN	II: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ	1BI6Z)	PYRIDOXINE HYDROCHLOR	RIDE	6 mg in 5 mL
DEXPANTHENOL ()	UNII: 106C93RI7Z)	(DEXPANTHENOL - UNII:106C93RI7Z)		DEXPANTHEN	IOL	15 mg in 5 mL
Inactive Ingred	lients					
		Ingredient Name				Strength
PROPYLENE GLYC	COL (UNII: 6DC9Q	167V3)				
GENTISIC ACID ET	HANOLAMIDE (U	NII: H4E039OIGX)				
SO DIUM HYDRO XI						
POLYSORBATE 80						
POLYSORBATE 20		·				
BUTYLATED HYDR BUTYLATED HYDR						
Packaging						
# Item Code		Package Description	Mar	keting Start Date	Mai	rketing End Date
1 NDC:61703-426-	50 mL in 1 VIAL, 1	MULTI-DOSE; Type 0: Not a Combination				
01	Product					
	Product		arketin	g Start Date	Market	ting End Date
Marketing Ir	Product	on Number or Monograph Citation Ma	arke tin g 27/20 15	g Start Date	Market	ting End Date
Marketing Ir	Product nformation ory Applicatio	on Number or Monograph Citation Ma		g Start Date	Market	ting End Date
Marketing Ir Marketing Catego NDA	Product nformation ory Applicatio	on Number or Monograph Citation Ma		g Start Date	Market	ting End Dat
Marketing Ir Marketing Catego NDA Part 2 of 2	Product fory Applicatio NDA021625	on Number or Monograph Citation Ma 0 1/2		g Start Date	Market	ting End Dat
Marketing Ir Marketing Catego NDA Part 2 of 2 BIOTIN, FO	Product for mation Application NDA021625 LIC ACID, A	on Number or Monograph Citation Ma		g Start Date	Market	ting End Date
Marketing Ir Marketing Catego NDA Part 2 of 2 BIOTIN, FO	Product for mation Application NDA021625 LIC ACID, A	on Number or Monograph Citation Ma 0 1/2 AND CYANOCOBALAMIN		g Start Date	Market	ting End Dat
Marketing Ir Marketing Catego NDA Part 2 of 2 BIOTIN, FO	Product fory Application NDA021625 LIC ACID, A and cyanocobala	on Number or Monograph Citation Ma 0 1/2 AND CYANOCOBALAMIN		g Start Date	Market	ting End Date
Marketing Ir Marketing Catego NDA Part 2 of 2 BIOTIN, FO biotin, folic acid, a Product Inform	Product for mation Application NDA021625 LIC ACID, A and cyanocobala	on Number or Monograph Citation Ma 0 1/2 AND CYANOCOBALAMIN		g Start Date	Marke	ting End Date
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Marketing Ir Marketing Catego NDA Part 2 of 2 BIOTIN, FO biotin, folic acid, a	Product Product Application NDA021625 LIC ACID, A and cyanocobala hation e)	on Number or Monograph Citation Ma 0 1/2 AND CYANOCOBALAMIN amin injection, solution, concentrate		g Start Date	Marke	ting End Date
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Marketing Ir Marketing Catego NDA Part 2 of 2 BIOTIN, FO biotin, folic acid, a Product Inform Item Code (Source Route of Administ	Product for mation Application NDA021625 LIC ACID, A and cyanocobala hation e) tration ent/Active Moie Ing	AND CYANOCOBALAMIN amin injection, solution, concentrate NDC:6 1703-430 INTRAVENOUS	27/20 15	Basis of Stre		ting End Dat
Marketing Ir Marketing Catego NDA Part 2 of 2 BIOTIN, FO biotin, folic acid, a Product Inform Item Code (Sourc Route of Administ Active Ingredie BIOTIN (UNII: 6506	Product Product Product Application NDA021625 LIC ACID, A and cyanocobala ation e) tration ent/Active Moie Ing 5U10H04) (BIOTIN	AND CYANOCOBALAMIN amin injection, solution, concentrate NDC:61703-430 INTRAVENOUS	27/20 15	Basis of Stre BIOTIN	ength	Strength 60 ug in 5 mL
Marketing Ir Marketing Catego NDA Part 2 of 2 BIOTIN, FO biotin, folic acid, Product Inform Item Code (Source Route of Administ Active Ingredie BIOTIN (UNII: 6 SOE FOLIC ACID (UNII: 5	Product Product Product Application NDA021625 LIC ACID, A and cyanocobala and cyanocobala ation e) tration e) tration e) tration fung 5010604) (BIOTIN 935E97BOY8) (FO	AND CYANOCOBALAMIN amin injection, solution, concentrate NDC:6 1703-430 INTRAVENOUS	27/20 15	Basis of Stre	ength	

ents		
Ingredient Name		Strength
)L (UNII: 6DC9Q167V3)		
HYDRATE (UNII: 2968PHW8QP)		
J NSPECIFIED FORM (UNII: 1Q73Q2JULR)		
E (UNII: 55X04QC32I)		
Package Description	Marketing Start Date	Marketing End Date
	n	
formation		
ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA021625	0 1/27/20 15	
formation		
ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	0 1/27/20 15	
	DL (UNII: 6DC9Q167V3) HYDRATE (UNII: 2968PHW8QP) UNSPECIFIED FORM (UNII: 1Q73Q2JULR) DE (UNII: 55X04QC32I) Package Description 50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combinatio Product formation ry Application Number or Monograph Citation NDA021625 formation	DL (UNII: 6DC9Q167V3) HYDRATE (UNII: 2968PHW8QP) UNSPECIFIED FORM (UNII: 1Q73Q2JULR) DE (UNII: 55X04QC321) The package Description Package Description S0 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product Marketing Start Date Marketing Start Date 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product Marketing Start Date 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product Marketing Start Date 1 VIAL, MULTI-DOSE; Type 0: Not a Combination 1 VIAL, MULTI-DOSE; VIAL, MULTI-DOSE; Type 0: Not a Combination 1 VIAL, MULTI-DOSE; Type 0: Not a Combination 1 VIAL, MULTI-DOSE; VIAL, MULTI-DOSE; VIAL, MULTI-DOSE

M.V.I. ADULT

retinol, ergocalciferol, .alpha.-tocopherol acetate, dl-, phytonadione, ascorbic acid, niacinamide, riboflavin 5phosphate sodium, thiamine hydrochloride, pyridoxine hydrochloride, dexpanthenol, biotin, folic acid, and cyanocobalamin kit

r rouuct m	formation			
Product T yp	e HU	JMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:61703-434
Packaging				
# Item	1 Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:61703	-434-82	10 in 1 PACKAGE	04/28/2017	
1 NDC:61703	-434-01	1 in 1 KIT		
Quantity of	f Parts			
Part # Package Quantity		Total Prod	uct Quantity	
Part #	Part 1 1 VIAL, SINGLE-DOSE		5 mL	
	Part 2 1 VIAL, SINGLE-DOSE			

Part 1 of 2

PHYTONADIONE, AS PHOSPHATE SODIUM HYDROCHLORIDE, A	CIFEROL, .ALPHATOCOPHER CORBIC ACID, NIACINAMIDE, R I, THIAMINE HYDROCHLORIDE ND DEXPANTHENOL ocopherol acetate, dl-, phytonadione, ascorbic a	IBOFLAVII , PYRIDOX	N 5- INE
	lrochloride, pyridoxine hydrochloride, and dexpa		
Product Information			
Item Code (Source)	NDC:61703-426		
Route of Administration	INTRAVENOUS		
Active Ingredient/Active M	oiety		
]	ngredient Name	Basis of Stre	ngth Strength
RETINOL (UNII: G2SH0XKK91) (RE	CTINOL (UNII: G2SH0XKK91) (RETINOL - UNII:G2SH0XKK91) RETINOL		1 mg in 5 mL
ERGOCALCIFEROL (UNII: VS041H	42XC) (ERGOCALCIFEROL - UNII:VS041H42XC)	ERGOCALCIFERO	OL 5 ug in 5 mL
.ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHATOCOPHEROL, DL UNII:7QWA1RIO01).ALPHA DL-			HEROL, 10 mg in 5 mL
PHYTONADIONE (UNII: A034SE7857) (PHYTONADIONE - UNII:A034SE7857)			150 ug in 5 mL
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R) ASC			200 mg in 5 mL
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4) NIACINAMIDE			
RIBOFLAVIN 5'-PHOSPHATE SODIUM (UNII: 20 RD1DZH99) (FLAVINFLAVINMONONUCLEOTIDE - UNII:7N464URE7E)MONONUCLEOTIDE			3.6 mgIDEin 5 mL
THIAMINE HYDRO CHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J) THIAMINE		6 mg in 5 mL	
PYRIDO XINE HYDRO CHLO RIDE (UNII: 68 Y4CF58 BV) (PYRIDO XINE - UNII:KV2JZ1BI6Z) PYRIDO XINE HYDRO CHLO RIDE		6 mg E in 5 mL	
DEXPANTHENOL (UNII: 106C93RI7	Z) (DEXPANTHENOL - UNII:106C93RI7Z)	DEXPANTHENOL	15 mg in 5 mL
Inactive Ingredients			Strength
Ingredient Name			
PROPYLENE GLYCOL (UNII: 6 DC9 GENTISIC ACID ETHANOLAMIDE			
SODIUM HYDROXIDE (UNII: 55X04			
POLYSORBATE 80 (UNII: 6OZP392			
POLYSORBATE 20 (UNII: 7T1F30V	,		
BUTYLATED HYDRO XYTO LUENE			
	(UNII: REK4960K2U)		

Packaging					
# Item Code		Package Description	Mar	keting Start Date	Marketing End Date
NDC:61703-426- 02	5 mL in 1 VIAL, S Product	NGLE-DOSE; Type 0: Not a Combination		Dutt	Date
	110 ddel				
Marketing Ir	formation				
Marketing Catego		n Number or Monograph Citation	Marketin	g Start Date M	arketing End Dat
NDA	NDA021625		04/28/2017		0
Part 2 of 2					
BIOTIN, FO	LIC ACID,	AND CYANOCOBALAMI	N		
biotin, folic acid,	and cyanocobala	min injection, solution, concentrate	2		
Product Inform					
Item Code (Sourc	e)	NDC:61703-430			
Route of Administ	ration	INTRAVENOUS			
Active Ingredie					
	-	redient Name		Basis of Streng	
		- UNII:6SO6U10H04)		BIOTIN	60 ug in 5 mL
		LIC ACID - UNII:935E97BOY8)		FOLIC ACID	600 ug in 5 m
CYANOCOBALAMI	IN (UNII: P6 YC3EG	204) (CYANOCOBALAMIN - UNII:P6 YC31	EG204)	CYANOCOBALAN	/IIN 5 ug in 5 mL
Inactive Ingred	ionts				
macuve ingreu	ients	Ingredient Name			Strength
PROPYLENE GLYC	OL (UNII: 6DC9Q				Strength
CITRIC ACID MON					
		RM (UNII: 1Q73Q2JULR)			
SO DIUM HYDRO XI	DE (UNII: 55X04Q0	2321)			
Packaging					
		Package Description	Mar	keting Start Date	Marketing End Date
 First State State	5 mL in 1 VIAL, S Product	Package Description INGLE-DOSE; Type 0: Not a Combination		•	-
# Item Code 1 NDC:61703-430-				•	-
# Item Code 1 NDC:61703-430-	Product			•	-

NDA	NDA021625	04/28/2017		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA021625	04/28/2017		

Labeler - Hospira, Inc. (141588017)

Establishment				
Name	Address	ID/FEI	Business Operations	
Hospira, Inc.		093132819	ANALYSIS(61703-422, 61703-434), LABEL(61703-422, 61703-434), MANUFACTURE(61703-422, 61703-434), PACK(61703-422, 61703-434)	

Revised: 2/2020

Hospira, Inc.