

**PEDIATRIC INFUVITE MULTIPLE VITAMINS- ascorbic acid, vitamin a palmitate, cholecalciferol, thiamine hydrochloride, riboflavin-5 phosphate sodium, pyridoxine hydrochloride, niacinamide, dexpanthenol, alpha-tocopherol acetate, vitamin k1, folic acid, biotin, cyanocobalamin**  
**PEDIATRIC INFUVITE MULTIPLE VITAMINS- ascorbic acid, vitamin a palmitate, cholecalciferol, thiamine hydrochloride, riboflavin-5 phosphate sodium, pyridoxine hydrochloride, niacinamide, dexpanthenol, alpha-tocopherol acetate, vitamin k1, folic acid, biotin, cyanocobalamin injection, solution**  
**Sandoz Inc**

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#### **HIGHLIGHTS OF PRESCRIBING INFORMATION**

**These highlights do not include all the information needed to use INFUVITE PEDIATRIC safely and effectively. See full prescribing information for INFUVITE PEDIATRIC. INFUVITE PEDIATRIC (multiple vitamins injection), for intravenous use**  
**Initial U.S. Approval: 2001**

#### **INDICATIONS AND USAGE**

INFUVITE PEDIATRIC is a combination of vitamins indicated for the prevention of vitamin deficiency in pediatric patients up to 11 years of age receiving parenteral nutrition (1)

#### **DOSAGE AND ADMINISTRATION**

- INFUVITE PEDIATRIC is a combination product that contains the following vitamins: ascorbic acid, vitamin A, vitamin D, thiamine, riboflavin, pyridoxine, niacinamide, dexpanthenol, vitamin E, vitamin K1, folic acid, biotin, and vitamin B12 (2.1)
- INFUVITE PEDIATRIC is for administration by intravenous infusion after dilution (2.1)
- Recommended daily dosage is based on patient's actual weight (2.2):
  - **INFUVITE PEDIATRIC Single Dose:**
    - **Weight less than 1 kg:** 1.2 mL of Vial 1 and 0.3 mL of Vial 2
    - **Weight 1 kg to less than 3 kg:** 2.6 mL of Vial 1 and 0.65 mL Vial 2
    - **Weight 3 kg or greater:** 4 mL of Vial 1 and 1 mL of Vial 2
  - **INFUVITE PEDIATRIC Pharmacy Bulk Package:**
    - **Weight less than 1 kg:** 1.5 mL of combined content of Vials 1 and 2
    - **Weight 1 kg to less than 3 kg:** 3.25 mL of combined content of Vials 1 and 2
    - **Weight 3 kg or greater:** 5 mL of combined content of Vials 1 and 2.
- Supplemental vitamin A may be required for low-birth weight infants (2.2)
- INFUVITE PEDIATRIC is supplied as a single dose and as a pharmacy bulk package:
  - **Single Dose** consists of two vials labeled Vial 1 and Vial 2. Add one daily dose of Vial 1 and one daily dose of Vial 2 directly to at least 100 mL of intravenous dextrose or saline solution prior to intravenous use (2.3)
  - **Pharmacy Bulk Package** consists of two vials labeled Vial 1 and Vial 2. Transfer contents of Vial 2 to contents of Vial 1. Then, take 1.5 mL, 3.25 mL, or 5 mL from mixture and add to at least 100 mL of intravenous dextrose or saline solution prior to intravenous use (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**

- INFUVITE PEDIATRIC single dose is an injection consisting of two vials labeled Vial 1 (4 mL) and Vial 2 (1 mL) (3)
- INFUVITE PEDIATRIC pharmacy bulk package is an injection consisting of two vials labeled Vial 1 (50 mL) and Vial 2 (10 mL) (3)

- See Full Prescribing Information for vitamin strengths (11)

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### CONTRAINDICATIONS

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- Hypersensitivity to any of vitamins or excipients (4)
- Existing hypervitaminosis (4)

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### WARNINGS AND PRECAUTIONS

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- *Risk of Aluminum Toxicity:* For at risk patients (renal failure or those with prolonged therapy), consider periodic monitoring of aluminum levels (5.1)
- *Allergic Reactions:* To thiamine may occur (5.2)
- *Hypervitaminosis A:* Patients with renal failure or liver disease may be at higher risk (5.3)
- *Decreased Anticoagulant Effect of Warfarin:* Monitor INR (5.4, 7.1)
- *Interferes with Megaloblastic Anemia Diagnosis:* Avoid during testing for this disorder (5.5)
- *Risk of Vitamin Deficiencies or Excesses:* Monitor blood vitamin concentrations (5.6)
- *False Negative Urine Glucose Tests:* Due to vitamin C (5.7)
- *Risk of Vitamin E Toxicity:* Additional oral and parenteral vitamin E may result in elevated vitamin E blood concentrations in infants (5.8)
- *Low Vitamin A Levels:* Monitor vitamin A levels (5.9)
- *Risk of E-Ferol Syndrome:* Due to polysorbates (5.10)

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### ADVERSE REACTIONS

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

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

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### DRUG INTERACTIONS

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Effect of INFUVITE PEDIATRIC on other drugs:

- *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)
- *Levodopa:* Pyridoxine may decrease blood levels of levodopa and levodopa efficacy may decrease (7.1)
- *Phenytoin:* Folic acid may decrease phenytoin blood levels and increase risk of seizure activity (7.1)
- *Methotrexate:* Folic acid may decrease response to methotrexate (7.1)

Effects of other drugs on INFUVITE PEDIATRIC:

- *Hydralazine, Isoniazid:* Concomitant administration of hydralazine or isoniazid may increase pyridoxine requirements (7.2).
- *Phenytoin:* May decrease folic acid concentrations (7.2)

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### USE IN SPECIFIC POPULATIONS

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- *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.

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## **FULL PRESCRIBING INFORMATION**

### **1 INDICATIONS AND USAGE**

INFUVITE PEDIATRIC is a combination of vitamins indicated for the prevention of vitamin deficiency in pediatric patients up to 11 years of age 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 Instructions

INFUVITE PEDIATRIC is a combination product that contains the following vitamins: ascorbic acid, vitamin A, vitamin D, thiamine, riboflavin, pyridoxine, niacinamide, dexpanthenol, vitamin E, vitamin K1, folic acid, biotin, and vitamin B12.

INFUVITE PEDIATRIC is supplied as a single dose or as a pharmacy bulk package, for intravenous use intended for administration by intravenous infusion after dilution:

- INFUVITE PEDIATRIC **Single Dose** consists of two vials. A weight-based volume from each vial must be added directly to dextrose or saline solution prior to intravenous administration [see *Dosage and Administration* (2.2, 2.3)].
- INFUVITE PEDIATRIC **Pharmacy Bulk Package** consists of two pharmacy bulk vials which must be mixed prior to use. The mixed solution will provide multiple daily doses which must be diluted prior to intravenous administration. Pharmacy bulk package of INFUVITE PEDIATRIC 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* (2.2, 2.3)].

## 2.2 Dosage Information

The recommended daily dosage volume is based on the patient's actual weight less than 1 kg, 1 kg to less than 3 kg, and 3 kg or greater.

Patients with multiple vitamin deficiencies or with increased vitamin requirements may need multiple daily dosages as indicated or additional doses of individual vitamins. Supplemental vitamin A may be required for low-birth weight infants.

Additional daily dosages of Vitamin E in infants are not recommended [see *Warnings and Precautions* (5.8)].

INFUVITE PEDIATRIC **Single Dose** (see Table 1):

One daily dose of Vial 1 (1.2 mL, 2.6 mL or 4 mL) and one daily dose of Vial 2 (0.3 mL, 0.65 mL or 1 mL) based on the patient's weight are added directly to a specified volume of an intravenous fluid [see *Dosage and Administration* (2.3)] (see Table 1).

**Table 1: Recommended Weight-Based Dosage of INFUVITE PEDIATRIC Single Dose**

|                                                           | <b>Less than 1 kg</b>  | <b>1 kg to less than 3 kg</b> | <b>3 kg or greater</b>   |
|-----------------------------------------------------------|------------------------|-------------------------------|--------------------------|
| <b>Daily Dosage Volume - Vial 1</b>                       | <b>1.2 mL</b>          | <b>2.6 mL</b>                 | <b>4 mL</b>              |
| Ascorbic acid (Vitamin C)                                 | 24 mg                  | 52 mg                         | 80 mg                    |
| Vitamin A (as palmitate)                                  | 690 IU (equals 0.2 mg) | 1495 IU (equals 0.5 mg)       | 2,300 IU (equals 0.7 mg) |
| Vitamin D <sub>3</sub> (cholecalciferol)                  | 120 IU (equals 3 mcg)  | 260 IU (equals 7 mcg)         | 400 IU (equals 10 mcg)   |
| Thiamine (Vitamin B <sub>1</sub> ) (as the hydrochloride) | 0.4 mg                 | 0.8 mg                        | 1.2 mg                   |
| Riboflavin (Vitamin B <sub>2</sub> )                      |                        |                               |                          |

|                                                       |                      |                      |                    |
|-------------------------------------------------------|----------------------|----------------------|--------------------|
| (as riboflavin 5-phosphate sodium)                    | 0.4 mg               | 0.9 mg               | 1.4 mg             |
| Pyridoxine HCl (Vitamin B <sub>6</sub> )              | 0.3 mg               | 0.7 mg               | 1 mg               |
| Niacinamide                                           | 5.1 mg               | 11.1 mg              | 17 mg              |
| Dexpanthenol (as <i>d</i> -pantothenyl alcohol)       | 1.5 mg               | 3.3 mg               | 5 mg               |
| Vitamin E ( <i>dl</i> - $\alpha$ -tocopheryl acetate) | 2.1 IU (equals 2 mg) | 4.6 IU (equals 5 mg) | 7 IU (equals 7 mg) |
| Vitamin K <sub>1</sub>                                | 0.1 mg               | 0.1 mg               | 0.2 mg             |
| <b>Daily Dosage Volume - Vial 2</b>                   | <b>0.3 mL</b>        | <b>0.65 mL</b>       | <b>1 mL</b>        |
| Folic acid                                            | 42 mcg               | 91 mcg               | 140 mcg            |
| Biotin                                                | 6 mcg                | 13 mcg               | 20 mcg             |
| Vitamin B12 (cyanocobalamin)                          | 0.3 mcg              | 0.7 mcg              | 1 mcg              |

INFUVITE PEDIATRIC **Pharmacy Bulk Package** (see Table 2):

The recommended daily dosage volume of combined content of vials 1 and 2 (1.5 mL, 3.25 mL or 5 mL) is based on the patient's weight and then added directly to the specific volume of an intravenous fluid [see *Dosage and Administration (2.3)*].

**Table 2: Recommended Weight-Based Dosage of INFUVITE PEDIATRIC Pharmacy Bulk Package**

|                                                                         | <b>Less than 1 kg</b>  | <b>1 kg to less than 3 kg</b> | <b>3 kg or greater</b>   |
|-------------------------------------------------------------------------|------------------------|-------------------------------|--------------------------|
| <b>Daily Dosage Volume (combined contents of Vial 1 and Vial 2)</b>     | <b>1.5 mL</b>          | <b>3.25 mL</b>                | <b>5 mL</b>              |
| Ascorbic acid (Vitamin C)                                               | 24 mg                  | 52 mg                         | 80 mg                    |
| Vitamin A (as palmitate)                                                | 690 IU (equals 0.2 mg) | 1495 IU (equals 0.5 mg)       | 2,300 IU (equals 0.7 mg) |
| Vitamin D <sub>3</sub> (cholecalciferol)                                | 120 IU (equals 3 mcg)  | 260 IU (equals 7 mcg)         | 400 IU (equals 10 mcg)   |
| Thiamine (Vitamin B <sub>1</sub> ) (as the hydrochloride)               | 0.4 mg                 | 0.8 mg                        | 1.2 mg                   |
| Riboflavin (Vitamin B <sub>2</sub> ) (as riboflavin 5-phosphate sodium) | 0.4 mg                 | 0.9 mg                        | 1.4 mg                   |
| Pyridoxine HCl (Vitamin B <sub>6</sub> )                                | 0.3 mg                 | 0.7 mg                        | 1 mg                     |
| Niacinamide                                                             | 5.1 mg                 | 11.1 mg                       | 17 mg                    |
| Dexpanthenol (as <i>d</i> -pantothenyl alcohol)                         | 1.5 mg                 | 3.3 mg                        | 5 mg                     |

|                                                       |                      |                      |                    |
|-------------------------------------------------------|----------------------|----------------------|--------------------|
| Vitamin E ( <i>dl</i> - $\alpha$ -tocopheryl acetate) | 2.1 IU (equals 2 mg) | 4.6 IU (equals 5 mg) | 7 IU (equals 7 mg) |
| Vitamin K <sub>1</sub>                                | 0.1 mg               | 0.1 mg               | 0.2 mg             |
| Folic acid                                            | 42 mcg               | 91 mcg               | 140 mcg            |
| Biotin                                                | 6 mcg                | 13 mcg               | 20 mcg             |
| Vitamin B12 (cyanocobalamin)                          | 0.3 mcg              | 0.7 mcg              | 1 mcg              |

### 2.3 Preparation and Administration Instructions

Do not administer INFUVITE PEDIATRIC as a direct, undiluted intravenous injection as it may cause dizziness, faintness, and possible tissue irritation.

#### INFUVITE PEDIATRIC Single Dose:

- Use only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).  
Add one weight-based dose of Vial 1 (1.2 mL, 2.6 mL or 4 mL) and one weight-based dose of Vial 2 (0.3 mL, 0.65 mL or 1 mL) directly to at least 100 mL of intravenous dextrose or saline solution.
- Discard unused portion.
- Visually inspect for particulate matter and discoloration prior to administration.
- After INFUVITE PEDIATRIC 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 INFUVITE PEDIATRIC, particularly A, D and riboflavin, are light sensitive.

#### INFUVITE PEDIATRIC Pharmacy Bulk Package:

- Use only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).
- Transfer the contents of Vial 2 (10 mL of solution) into the contents of Vial 1 (40 mL of solution). The mixed solution (50 mL) will provide thirty-three 1.5 mL single doses, fifteen 3.25 mL single doses or ten 5 mL single doses.
- 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 should be completed within 4 hours. The mixed solution may be refrigerated and stored for up to 4 hours.
- Discard unused portion.
- Visually inspect for particulate matter and discoloration prior to administration.
- Add one dose directly to at least 100 mL of intravenous dextrose or saline solution for each patient.
- After INFUVITE PEDIATRIC 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 INFUVITE PEDIATRIC, 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

- INFUVITE PEDIATRIC 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, tetracycline HCl and chlorothiazide sodium.
- Folic acid is unstable in the presence of calcium salts such as calcium gluconate.
- Vitamin A and thiamine in INFUVITE PEDIATRIC may react with bisulfite solutions such as sodium bisulfite or vitamin K bisulfite.
- Do not add INFUVITE PEDIATRIC directly to intravenous fat emulsions.
- Consult appropriate references for additional listings of physical and chemical compatibility of solutions and drugs with the vitamin infusion when needed. If incompatibilities are identified, avoid admixture or Y-site administration with vitamin solutions.

## 3 DOSAGE FORMS AND STRENGTHS

INFUVITE PEDIATRIC **Single Dose** is an injection consisting of two single-dose vials labeled Vial 1 (4 mL) and Vial 2 (1 mL). For the vitamin strengths [see *Dosage and Administration (2.2) and Description (11)*].

INFUVITE PEDIATRIC **Pharmacy Bulk Package** is an injection consisting of two vials labeled Vial 1 (40 mL Fill in 50 mL Vial) and Vial 2 (10 mL). The mixed solution (50 mL) will provide thirty-three 1.5 mL single doses, fifteen 3.25 mL single doses or ten 5 mL single doses. For the vitamin strengths [see *Dosage and Administration (2.2) and Description (11)*].

## 4 CONTRAINDICATIONS

INFUVITE PEDIATRIC is contraindicated in patients who have:

- An existing hypervitaminosis, or
- A history of hypersensitivity to any vitamins or excipients contained in this formulation.

## 5 WARNINGS AND PRECAUTIONS

### 5.1 Aluminum Toxicity

INFUVITE PEDIATRIC contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration in pediatric patients with renal impairment. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solution, 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. To prevent aluminum toxicity periodically monitor aluminum levels with prolonged parenteral administration of INFUVITE PEDIATRIC.

## **5.2 Allergic Reactions to Thiamine**

Allergic reactions such as urticaria, shortness of breath, wheezing and angioedema have been reported following intravenous administration of thiamine, which is found in INFUVITE PEDIATRIC. There have been rare reports of anaphylaxis following intravenous doses of thiamine. No fatal anaphylaxis associated with INFUVITE PEDIATRIC has been reported.

## **5.3. 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 disease with vitamin A, an ingredient found in INFUVITE PEDIATRIC, should be undertaken with caution [see *Use in Specific Populations (8.6, 8.7)*]. Blood levels of Vitamin A should be monitored periodically.

## **5.4 Decreased Anticoagulant Effect of Warfarin**

INFUVITE PEDIATRIC contains Vitamin K which may decrease the anticoagulant action of warfarin. In patients who are on warfarin anticoagulant therapy receiving INFUVITE PEDIATRIC monitor blood levels of prothrombin/INR to determine if dose of warfarin needs to be adjusted.

## **5.5 Interference with Diagnosis of Megaloblastic Anemia**

INFUVITE PEDIATRIC contains folic acid and cyanocobalamin which can mask serum deficiencies of folic acid and cyanocobalamin in patients with megaloblastic anemia. Avoid the use of INFUVITE PEDIATRICALS in patients with suspected or diagnosed megaloblastic anemia prior to blood sampling for the detection of the folic acid and cyanocobalamin deficiencies.

## **5.6 Potential to Develop Vitamin Deficiencies or Excesses**

In patients receiving parenteral multivitamins such as with INFUVITE PEDIATRIC, blood vitamin concentrations should be periodically monitored to determine if vitamin deficiencies or excesses are developing. INFUVITE PEDIATRIC 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)*].

## **5.7 Interference with Urine Glucose Testing**

INFUVITE PEDIATRIC contains vitamin C which is also known as ascorbic acid. Ascorbic acid in the urine may cause false negative urine glucose results.

## **5.8 Vitamin E Overdose in Infants Receiving Additional Vitamin E**

Additional vitamin E supplementations of patients receiving INFUVITE PEDIATRIC may



result in elevated blood concentrations of vitamin E and potential vitamin E toxicity in infants. Avoid additional oral or parental doses of vitamin E in infants. Daily dose of INFUVITE PEDIATRIC contains adequate concentrations of vitamin E required to achieve normal blood levels of vitamin E.

### **5.9 Risk of Low Vitamin A Levels**

Lower vitamin A concentrations may occur after administration of INFUVITE PEDIATRIC due to the adherence of Vitamin A to plastic. Monitor blood vitamin A concentrations periodically. Additional administration of therapeutic doses of vitamin A may be required, especially in low-birth weight infants.

### **5.10 Risk of E-Ferol Syndrome in Low-Birth Weight Infants**

E-Ferol syndrome manifested by thrombocytopenia, renal dysfunction, hepatomegaly, cholestasis, ascites, hypotension and metabolic acidosis has been reported in low-birth weight infants following administration of polysorbates which are found in INFUVITE PEDIATRIC. No E-Ferol syndrome associated with INFUVITE PEDIATRIC has been reported.

## **6 ADVERSE REACTIONS**

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

- Allergic reactions to thiamine [see *Warnings and Precautions (5.2)*].
- Hypervitaminosis A [see *Warnings and Precautions (5.3)*]

The following adverse reactions have been identified during postapproval use of INFUVITE PEDIATRIC. 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, pruritis  
*CNS:* headache, dizziness, agitation, anxiety  
*Ophthalmic:* diplopia

## **7 DRUG INTERACTIONS**

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

### **7.1 Drug Interactions Affecting Co-administered Drugs**

Warfarin: Vitamin K, a component of INFUVITE PEDIATRIC, antagonizes the anticoagulant action of warfarin. In patients who are co-administered warfarin and INFUVITE PEDIATRIC, blood levels of prothrombin/INR should be monitored to determine if dose of warfarin needs to be adjusted [see *Warnings and Precautions (5.4)*].

Antibiotics: Thiamine, riboflavin, pyridoxine, niacinamide, and ascorbic acid decrease antibiotic activities of erythromycin, kanamycin, streptomycin, doxycycline, and

lincomycin.

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

Levodopa: Pyridoxine may increase the metabolism of levodopa (decrease blood levels of levodopa) and decrease its efficacy.

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

Methotrexate: Folic acid may decrease a patient's response to methotrexate therapy.

## 7.2 Drug Interactions Affecting Vitamin Levels

Hydralazine, Isoniazid: Concomitant administration of hydralazine or isoniazid may increase pyridoxine requirements.

Phenytoin: Phenytoin may decrease serum folic acid concentrations.

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

Pregnancy Category C.

INFUVITE PEDIATRIC 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 non-pregnant women. Animal reproduction studies have not been conducted with INFUVITE PEDIATRIC (multiple vitamins injection).

### 8.3 Nursing Mothers

INFUVITE PEDIATRIC has not been studied in nursing mothers. Lactating women may have vitamin requirements that exceed those of non-lactating women. Caution should be exercised when INFUVITE PEDIATRIC is administered to nursing mothers.

### 8.4 Pediatric Use

INFUVITE PEDIATRIC is approved for the prevention of vitamin deficiency in pediatric patients up to 11 years old receiving parenteral nutrition. INFUVITE PEDIATRIC has not been studied in pediatric patients older than 11 years.

INFUVITE PEDIATRIC contains aluminum that may be toxic for premature neonates. Aluminum levels should be monitored periodically during administration of INFUVITE PEDIATRIC to premature neonates [see *Warnings and Precautions (5.1)*].

Additional vitamin E supplementations of infants receiving INFUVITE PEDIATRIC may result in elevated blood concentrations of vitamin E and potential vitamin E toxicity [see *Warnings and Precautions (5.8)*].

E-Ferol syndrome has been reported in low-birth weight infants following administration of polysorbates which are found in INFUVITE PEDIATRIC. No E-Ferol syndrome associated with INFUVITE PEDIATRIC has been reported [see *Warnings and Precautions (5.10)*].

## 8.6 Renal Impairment

INFUVITE PEDIATRIC 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, 5.3)*].

## 8.7 Hepatic Impairment

INFUVITE PEDIATRIC has not been studied in patients with liver impairment. Monitor vitamin A levels in patients with liver disease [see *Warnings and Precautions (5.3)*].

## 10 OVERDOSAGE

Signs and symptoms of acute or chronic overdosage may be those of individual INFUVITE PEDIATRIC component toxicity. There is no clinical experience with INFUVITE PEDIATRIC overdosage.

## 11 DESCRIPTION

INFUVITE PEDIATRIC (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:

INFUVITE PEDIATRIC (multiple vitamins injection) supplied as single dose consists of:

- (a) Vial 1 (4 mL); and
- (b) Vial 2 (1 mL).

Vial 1 will provide one daily dose of 1.2 mL, 2.6 mL or 4 mL and Vial 2 will provide one daily dose of 0.3 mL, 0.65 mL or 1 mL [see *Dosage and Administration (2.2)*].

INFUVITE PEDIATRIC (multiple vitamins injection) supplied as pharmacy bulk package consists of:

- (a) Vial 1 (40 mL Fill in 50 mL Vial); and
- (b) Vial 2 (10 mL).

The mixed solution will provide many single doses [see *Dosage and Administration (2.2)*].

Each 4 mL of Vial 1 contains 10 vitamins and each 1 mL of Vial 2 contains 3 vitamins (see Table 3).

**Table 3: INGREDIENTS IN INFUVITE PEDIATRIC FORMULATION**

| Vial 1                                     |                             |
|--------------------------------------------|-----------------------------|
| Active Ingredient                          | Quantity per 4 mL           |
| Ascorbic acid (Vitamin C)                  | 80 mg                       |
| Vitamin A* (as palmitate)                  | 2,300 IU<br>(equals 0.7 mg) |
| Vitamin D <sub>3</sub> * (cholecalciferol) | 400 IU (equals              |

|                                                                                                                                                                                                                                             |                          |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
|                                                                                                                                                                                                                                             | 10 mcg)                  |
| Thiamine (Vitamin B <sub>1</sub> ) (as the hydrochloride)                                                                                                                                                                                   | 1.2 mg                   |
| Riboflavin (Vitamin B <sub>2</sub> ) (as riboflavin 5-phosphate sodium)                                                                                                                                                                     | 1.4 mg                   |
| Pyridoxine HCl (Vitamin B <sub>6</sub> )                                                                                                                                                                                                    | 1 mg                     |
| Niacinamide                                                                                                                                                                                                                                 | 17 mg                    |
| Dexpanthenol (as <i>d</i> -pantothenyl alcohol)                                                                                                                                                                                             | 5 mg                     |
| Vitamin E* ( <i>dl</i> - $\alpha$ -tocopheryl acetate)                                                                                                                                                                                      | 7 IU (equals 7 mg)       |
| Vitamin K <sub>1</sub> *                                                                                                                                                                                                                    | 0.2 mg                   |
| *Polysorbate 80 is used to water solubilize the oil-soluble vitamins A, D, E, and K.<br>Inactive ingredients in 4 mL of Vial 1: 50 mg polysorbate 80, sodium hydroxide and/or hydrochloric acid for pH adjustment, and water for injection. |                          |
| <b>Vial 2</b>                                                                                                                                                                                                                               |                          |
| <b>Active Ingredient</b>                                                                                                                                                                                                                    | <b>Quantity per 1 mL</b> |
| Folic acid                                                                                                                                                                                                                                  | 140 mcg                  |
| Biotin                                                                                                                                                                                                                                      | 20 mcg                   |
| Vitamin B <sub>12</sub> (cyanocobalamin)                                                                                                                                                                                                    | 1 mcg                    |
| Inactive ingredients in 1 mL of Vial 2: 75 mg mannitol, citric acid and/or sodium citrate for pH adjustment and water for injection.                                                                                                        |                          |

INFUVITE PEDIATRIC (multiple vitamins injection) makes available a combination of oil-soluble and water-soluble vitamins in an aqueous solution, formulated for incorporation into intravenous solutions. The liposoluble vitamins A, D, E, and K have been solubilized in an aqueous medium with polysorbate 80, permitting intravenous administration of these vitamins.

INFUVITE PEDIATRIC contains no more than 30 mcg/L of aluminum (combined Vials 1 and 2).

## 13 NONCLINICAL TOXICOLOGY

### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity, mutagenicity, and fertility studies have not been performed with INFUVITE PEDIATRIC.

## 16 HOW SUPPLIED/STORAGE AND HANDLING

### How Supplied:

INFUVITE PEDIATRIC (multiple vitamins injection) is supplied as follows:

INFUVITE PEDIATRIC (multiple vitamins injection) **Single Dose:**

- NDC 54643-7886-1 - Boxes containing ten single dose vials – five each of Vial 1 (4 mL) and five each of Vial 2 (1 mL), one Vial 1 plus one Vial 2 to be used for a single dose [see *Dosage and Administration (2.2, 2.3)*].

INFUVITE PEDIATRIC (multiple vitamins injection) **Pharmacy Bulk Package:**

- NDC 54643-7898-0 - Boxes containing two vials – Vial 1 (40 mL Fill in 50 mL Vial) and Vial 2 (10 mL). Mixed contents of Vial 2 with Vial 1 provide thirty-three 1.5 mL single doses, fifteen 3.25 mL single doses or 10 single 5 mL doses [see *Dosage and Administration (2.2, 2.3)*].

### **Storage and Handling:**

Minimize exposure of INFUVITE PEDIATRIC to light because vitamins A, D and riboflavin are light sensitive.

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

## **17 PATIENT COUNSELING INFORMATION**

Instruct caregiver(s) and patients (if age appropriate):

- To watch for signs of allergic reactions such as urticaria, shortness of breath, wheezing and angioedema since hypersensitivity reactions may occur to any of the vitamins or excipients contained in INFUVITE PEDIATRIC.
- To watch for and immediately report nausea, vomiting, headache, dizziness, blurred vision, especially if patients have renal impairment, as these may be signs of hypervitaminosis A.
- To report other adverse reactions that patients may experience such as rash, erythema, pruritus, headache, dizziness, agitation, anxiety, and diplopia.
- Patients on warfarin anticoagulant therapy will be monitored periodically with 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 and the need to monitor renal function, calcium, phosphorus, aluminum and vitamin A levels in patients with renal impairment.
- That INFUVITE PEDIATRIC should be avoided in patients with suspected or diagnosed megaloblastic anemia prior to blood sampling for the detection of the folic acid and cyanocobalamin deficiencies.
- That vitamin C (ascorbic acid) contained in INFUVITE PEDIATRIC may cause false negative urine glucose results.

Manufactured by

**Sandoz Canada Inc.**

145 Jules-Léger Street

Boucherville, Qc, Canada, J4B 7K8

Distributed by

**Baxter Healthcare Corporation for PremierProRx®**

Clintec Nutrition Division

Deerfield, IL 60015 USA

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10-2016

## Vials Carton

2A9008PRORX

NDC 54643-7886-1

# INFUVITE® PEDIatric

Multiple Vitamins Injection

For intravenous infusion after dilution only.

Rx Only

**STERILE**

Contains 5 each of Vial 1 (4 mL) and Vial 2 (1 mL).

One vial of each to be used for a single dose.

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

**Vial 1** (4 mL)

**Vial 2** (1 mL)

**PREMIERProRx®**

2A9008PRORX NDC 54643-7886-1

INFUVITE PEDIatric

Multiple Vitamins Injection

For intravenous infusion after dilution only.

Sterile Rx only

Contains 5 each of Vial 1 (4 mL) and Vial 2 (1 mL).

One vial of each to be used for a single dose.

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

Vial 1 (4 mL)

Vial 2 (1 mL)

PremierProRx®

Pharmacy Bulk Package Carton

2A9061PRORX

PRESS

NDC 54643-7898-0

**INFUVITE® PEDIatric**  
**PHARMACY BULK PACKAGE**  
**Multiple Vitamins Injection**

**PHARMACY BULK PACKAGE**  
**NOT FOR DIRECT INFUSION**

For intravenous infusion after dilution only.

**STERILE**

**Rx Only**

Contents:

Vial 1 (40 mL fill in 50 mL Vial)

Vial 2 (10 mL).

Both vials combined produce 10 single doses.

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

**Vial 1 (40 mL)**

**Vial 2 (10 mL)**

**PREMIERProRx®**

2A9061 PRORX NDC 54643-7898-0

INFUVITE® PEDIatric

PHARMACY BULK PACKAGE

Multiple Vitamins Injection

PHARMACY BULK PACKAGE

NOT FOR DIRECT INFUSION

For intravenous infusion after dilution only.

STERILE Rx only

Contents: Vial 1 (40 mL fill in 50 mL) and

Vial 2 (10 mL).

Both vials combined produce 10 single doses.

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

Vial (40 mL)

Vial 2 (10 mL)

**PremierProRx®**

## PEDIATRIC INFUVITE MULTIPLE VITAMINS

ascorbic acid, vitamin a palmitate, cholecalciferol, thiamine hydrochloride, riboflavin-5 phosphate sodium, pyridoxine hydrochloride, niacinamide, dexpanthenol, alpha-tocopherol acetate, vitamin k1, folic acid, biotin, cyanocobalamin kit

### Product Information

|                     |                         |                           |                |
|---------------------|-------------------------|---------------------------|----------------|
| <b>Product Type</b> | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:54643-7898 |
|---------------------|-------------------------|---------------------------|----------------|

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--------------------------------------------------|----------------------|--------------------|
| 1 | NDC:54643-7898-0 | 1 in 1 CARTON; Type 0: Not a Combination Product | 12/23/2016           |                    |

### Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|------------------|------------------------|
| Part 1 | 1 VIAL           | 40 mL                  |
| Part 2 | 1 VIAL           | 10 mL                  |

### Part 1 of 2

## PEDIATRIC INFUVITE MULTIPLE VITAMINS

ascorbic acid, vitamin a palmitate, cholecalciferol, thiamine hydrochloride, riboflavin 5-phosphate sodium, pyridoxine hydrochloride, niacinamide, dexpanthenol, alpha-tocopherol acetate, vitamin k1 injection, solution



## Product Information

**Route of Administration** INTRAVENOUS

## Active Ingredient/Active Moiety

| Ingredient Name                                                                                    | Basis of Strength          | Strength             |
|----------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| <b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)                          | ASCORBIC ACID              | 80 mg<br>in 4 mL     |
| <b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC) (VITAMIN A - UNII:81G40H8B0T)                        | VITAMIN A                  | 2300 [iU]<br>in 4 mL |
| <b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)                      | CHOLECALCIFEROL            | 400 [iU]<br>in 4 mL  |
| <b>THIAMINE HYDROCHLORIDE</b> (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)                  | THIAMINE                   | 1.2 mg<br>in 4 mL    |
| <b>RIBOFLAVIN 5'-PHOSPHATE SODIUM</b> (UNII: 20RD1DZH99) (FLAVIN MONONUCLEOTIDE - UNII:7N464URE7E) | FLAVIN MONONUCLEOTIDE      | 1.4 mg<br>in 4 mL    |
| <b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)                  | PYRIDOXINE HYDROCHLORIDE   | 1 mg<br>in 4 mL      |
| <b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)                              | NIACINAMIDE                | 17 mg<br>in 4 mL     |
| <b>DEXPANTHENOL</b> (UNII: 1O6C93RI7Z) (DEXPANTHENOL - UNII:1O6C93RI7Z)                            | DEXPANTHENOL               | 5 mg<br>in 4 mL      |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)        | .ALPHA.-TOCOPHEROL ACETATE | 7 [iU]<br>in 4 mL    |
| <b>PHYTONADIONE</b> (UNII: A034SE7857) (PHYTONADIONE - UNII:A034SE7857)                            | PHYTONADIONE               | 0.2 mg<br>in 4 mL    |

## Inactive Ingredients

| Ingredient Name                             | Strength      |
|---------------------------------------------|---------------|
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)    | 50 mg in 4 mL |
| <b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)  |               |
| <b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB) |               |
| <b>WATER</b> (UNII: 059QF0KO0R)             |               |

## Packaging

| # | Item Code | Package Description                                | Marketing Start Date | Marketing End Date |
|---|-----------|----------------------------------------------------|----------------------|--------------------|
| 1 |           | 40 mL in 1 VIAL; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| NDA                | NDA021646                                | 01/29/2004           |                    |

# PEDIATRIC INFUVITE MULTIPLE VITAMINS

folic acid, biotin, cyanocobalamin injection, solution

## Product Information

**Route of Administration** INTRAVENOUS

## Active Ingredient/Active Moiety

| Ingredient Name                                                             | Basis of Strength | Strength       |
|-----------------------------------------------------------------------------|-------------------|----------------|
| <b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)         | FOLIC ACID        | 140 ug in 1 mL |
| <b>BIOTIN</b> (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)                 | BIOTIN            | 20 ug in 1 mL  |
| <b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204) | CYANOCOBALAMIN    | 1 ug in 1 mL   |

## Inactive Ingredients

| Ingredient Name                                            | Strength      |
|------------------------------------------------------------|---------------|
| <b>MANNITOL</b> (UNII: 3OWL53L36A)                         | 75 mg in 1 mL |
| <b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)            |               |
| <b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR) |               |
| <b>WATER</b> (UNII: 059QF0KO0R)                            |               |

## Packaging

| # | Item Code | Package Description                                | Marketing Start Date | Marketing End Date |
|---|-----------|----------------------------------------------------|----------------------|--------------------|
| 1 |           | 10 mL in 1 VIAL; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| NDA                | NDA021646                                | 01/29/2004           |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| NDA                | NDA021646                                | 01/29/2004           |                    |

# PEDIATRIC INFUVITE MULTIPLE VITAMINS

ascorbic acid, vitamin a palmitate, cholecalciferol, thiamine hydrochloride, riboflavin-5 phosphate

sodium, pyridoxine hydrochloride, niacinamide, dexpanthenol, alpha-tocopherol acetate, vitamin k1, folic acid, biotin, cyanocobalamin injection, solution

## Product Information

|                                |                         |                           |                |
|--------------------------------|-------------------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:54643-7886 |
| <b>Route of Administration</b> | INTRAVENOUS             |                           |                |

## Active Ingredient/Active Moiety

| Ingredient Name                                                                                     | Basis of Strength          | Strength             |
|-----------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| <b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)                           | ASCORBIC ACID              | 80 mg<br>in 5 mL     |
| <b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC) (VITAMIN A - UNII:81G40H8B0T)                         | VITAMIN A                  | 2300 [iU]<br>in 5 mL |
| <b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)                       | CHOLECALCIFEROL            | 400 [iU]<br>in 5 mL  |
| <b>THIAMINE HYDROCHLORIDE</b> (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)                   | THIAMINE                   | 1.2 mg<br>in 5 mL    |
| <b>RIBOFLAVIN 5'-PHOSPHATE SODIUM</b> (UNII: 20RD1DZ H99) (FLAVIN MONONUCLEOTIDE - UNII:7N464URE7E) | FLAVIN MONONUCLEOTIDE      | 1.4 mg<br>in 5 mL    |
| <b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ 1BI6Z)                  | PYRIDOXINE HYDROCHLORIDE   | 1 mg<br>in 5 mL      |
| <b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)                               | NIACINAMIDE                | 17 mg<br>in 5 mL     |
| <b>DEXPANTHENOL</b> (UNII: 1O6C93RI7Z) (DEXPANTHENOL - UNII:1O6C93RI7Z)                             | DEXPANTHENOL               | 5 mg<br>in 5 mL      |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ 1)        | .ALPHA.-TOCOPHEROL ACETATE | 7 [iU]<br>in 5 mL    |
| <b>PHYTONADIONE</b> (UNII: A034SE7857) (PHYTONADIONE - UNII:A034SE7857)                             | PHYTONADIONE               | 0.2 mg<br>in 5 mL    |
| <b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)                                 | FOLIC ACID                 | 140 ug<br>in 5 mL    |
| <b>BIOTIN</b> (UNII: 6S06U10H04) (BIOTIN - UNII:6S06U10H04)                                         | BIOTIN                     | 20 ug<br>in 5 mL     |
| <b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)                         | CYANOCOBALAMIN             | 1 ug in 5 mL         |

## Inactive Ingredients

| Ingredient Name                                            | Strength      |
|------------------------------------------------------------|---------------|
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)                   | 50 mg in 5 mL |
| <b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)            |               |
| <b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR) |               |
| <b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)                 |               |
| <b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)                |               |
| <b>WATER</b> (UNII: 059QF0KO0R)                            |               |
| <b>MANNITOL</b> (UNII: 3OWL53L36A)                         | 75 mg in 5 mL |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|   |           |                     |                      |                    |

|          |                  |                                                   |            |  |
|----------|------------------|---------------------------------------------------|------------|--|
| <b>1</b> | NDC:54643-7886-1 | 10 in 1 CARTON                                    | 12/23/2016 |  |
| <b>1</b> |                  | 5 mL in 1 VIAL; Type 0: Not a Combination Product |            |  |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| NDA                | NDA021265                                | 02/21/2001           |                    |

**Labeler** - Sandoz Inc (005387188)

Revised: 10/2016

Sandoz Inc