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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 $K_1$, folic acid, biotin, and vitamin $B_{12}$ (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 of 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 (40 mL fill in 50 mL) and Vial 2 (10 mL) (3)
- See Full Prescribing Information for vitamin strengths (11)

### ---------- CONTRAINDICATIONS ----------

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

### ---------- WARNINGS AND PRECAUTIONS ----------

- *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)

### ---------- ADVERSE REACTIONS ----------

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.**

### ---------- DRUG INTERACTIONS ----------

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)

### ---------- USE IN SPECIFIC POPULATIONS ----------

- *Pregnancy and Lactation*: Pregnant and lactating patients should follow the U.S. Recommended Daily Allowances for their condition, because their vitamin requirements may exceed those of nonpregnant and nonlactating patients (8.1, 8.2)
- *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: 11/2024**

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FULL PRESCRIBING INFORMATION: CONTENTS*



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

## 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 and Administration 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 $K_1$, folic acid, biotin, and vitamin $B_{12}$.

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 and 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 and 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)]*.

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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**

| | **Less than 1 kg** | **1 kg to less than 3 kg** | **3 kg or greater** |
|---|---|---|---|
| **Daily Dosage Volume – Vial 1** | **1.2 mL** | **2.6 mL** | **4 mL** |
| 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 $D_3$ (cholecalciferol) | 120 IU (equals 3 mcg) | 260 IU (equals 7 mcg) | 400 IU (equals 10 mcg) |
| Thiamine (Vitamin $B_1$) (as the hydrochloride) | 0.4 mg | 0.8 mg | 1.2 mg |
| Riboflavin (Vitamin $B_2$) (as riboflavin 5-phosphate sodium) | 0.4 mg | 0.9 mg | 1.4 mg |
| Pyridoxine HCl (Vitamin $B_6$) | 0.3 mg | 0.7 mg | 1 mg |
| Niacinamide | 5.1 mg | 11.1 mg | 17 mg |
| Dexpanthenol (as *d*-pantothenyl alcohol) | 1.5 mg | 3.3 mg | 5 mg |
| Vitamin E (*dl*-α-tocopheryl acetate) | 2.1 IU (equals 2 mg) | 4.6 IU (equals 5 mg) | 7 IU (equals 7 mg) |
| Vitamin $K_1$ | 0.1 mg | 0.1 mg | 0.2 mg |
| **Daily Dosage Volume – Vial 2** | **0.3 mL** | **0.65 mL** | **1 mL** |
| Folic acid | 42 mcg | 91 mcg | 140 mcg |
| Biotin | 6 mcg | 13 mcg | 20 mcg |
| Vitamin $B_{12}$ (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**

| | **Less than 1 kg** | **1 kg to less than 3 kg** | **3 kg or greater** |
|---|---|---|---|
| **Daily Dosage Volume (combined contents of Vial 1 and Vial 2)** | **1.5 mL** | **3.25 mL** | **5 mL** |
| 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 $D_3$ (cholecalciferol) | 120 IU (equals 3 mcg) | 260 IU (equals 7 mcg) | 400 IU (equals 10 mcg) |
| Thiamine (Vitamin $B_1$) (as the hydrochloride) | 0.4 mg | 0.8 mg | 1.2 mg |
| Riboflavin (Vitamin $B_2$) (as riboflavin 5-phosphate sodium) | 0.4 mg | 0.9 mg | 1.4 mg |
| Pyridoxine HCl (Vitamin $B_6$) | 0.3 mg | 0.7 mg | 1 mg |
| Niacinamide | 5.1 mg | 11.1 mg | 17 mg |

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| | | | |
|---|---|---|---|
| Dexpanthenol (as *d*-pantothenyl alcohol) | 1.5 mg | 3.3 mg | 5 mg |
| Vitamin E (*dl*-α-tocopheryl acetate) | 2.1 IU (equals 2 mg) | 4.6 IU (equals 5 mg) | 7 IU (equals 7 mg) |
| Vitamin $K_1$ | 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 $B_{12}$ (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.

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### 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)]*.

**Vial 1 (Single Dose and Pharmacy Bulk Package)** is supplied as clear, yellow to orange liquid in amber glass vial, closed with a rubber stopper, clear aluminum seal and a blue flip-off.

**Vial 2 (Single Dose and Pharmacy Bulk Package)** is supplied as clear, colorless to pale yellow liquid in amber glass vial closed with a rubber stopper, clear aluminum seal and pink flip-off.

## 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

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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 and 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 PEDIATRICS 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.

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# 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

Risk Summary
Administration of the approved recommended dose of INFUVITE PEDIATRIC in parental nutrition is not expected to cause major birth defects, miscarriage, or adverse maternal or fetal outcomes. Pregnant patients should follow the U.S. Recommended Daily Allowances for pregnancy because their vitamin requirements may exceed those of nonpregnant patients. Deficiency of essential vitamins may result in adverse pregnancy outcomes *(see Clinical Considerations)*. Animal reproduction studies have not been conducted with INFUVITE PEDIATRIC.

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The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Clinical Considerations

*Disease-associated Maternal and/or Embryo-Fetal Risk*

Deficiency of essential vitamins has been associated with adverse pregnancy and fetal outcomes, such as maternal folic acid deficiency and an increased risk of neural tube defects. Therefore, parenteral nutrition with multiple vitamins injection should be considered if a pregnant patient's nutritional requirements cannot be fulfilled by oral or enteral intake.

### 8.2 Lactation

Risk Summary

Multiple vitamins present in INFUVITE PEDIATRIC are also present in human milk. Administration of the approved recommended dose of Infuvite Pediatric in parental nutrition is not expected to cause harm to a breastfed infant. There is no information on the effects of Infuvite Pediatric on milk production. Lactating patients should follow the U.S. Recommended Daily Allowances for their condition, because their vitamin requirements may exceed those of nonlactating patients. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for INFUVITE PEDIATRIC and any potential adverse effects on the breastfed child from INFUVITE PEDIATRIC or from the underlying maternal condition.

### 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 and 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.

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# 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 (equals 0.7 mg) |
| Vitamin $D_3$* (cholecalciferol) | 400 IU (equals 10 mcg) |
| Thiamine (Vitamin $B_1$) (as the hydrochloride) | 1.2 mg |
| Riboflavin (Vitamin $B_2$) (as riboflavin 5-phosphate sodium) | 1.4 mg |
| Pyridoxine HCl (Vitamin $B_6$) | 1 mg |
| Niacinamide | 17 mg |
| Dexpanthenol (as *d*-pantothenyl alcohol) | 5 mg |
| Vitamin E* (*dl*-α-tocopheryl acetate) | 7 IU (equals 7 mg) |
| Vitamin $K_1$* | 0.2 mg |

*Polysorbate 80 is used to water solubilize the oil-soluble vitamins A, D, E, and K.

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.

| **Vial 2** | |
|---|---|
| **Active Ingredient** | **Quantity per 1 mL** |
| Folic acid | 140 mcg |
| Biotin | 20 mcg |
| Vitamin $B_{12}$ (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.

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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:

**Vial 1 (Single Dose and Pharmacy Bulk Package)** is supplied as clear, yellow to orange liquid in amber glass vial, closed with a rubber stopper, clear aluminum seal and a blue flip-off.

**Vial 2 (Single Dose and Pharmacy Bulk Package)** is supplied as clear, colorless to pale yellow liquid in amber glass vial closed with a rubber stopper, clear aluminum seal and pink flip-off.

INFUVITE PEDIATRIC **Single Dose:**

| | |
|---|---|
| Carton contains total ten single-dose vials | NDC 54643-5646-1 |
| Five of Vial 1 (4 mL) | NDC 54643-5648-1 |
| Five of Vial 2 (1 mL) | NDC 54643-5651-1 |

one Vial 1 plus one Vial 2 to be used for a single dose *[see Dosage and Administration (2.2 and 2.3)]*.

INFUVITE PEDIATRIC **Pharmacy Bulk Package:**

| | |
|---|---|
| Carton contains total two vials | NDC 54643-5647-0 |
| One Vial 1 (40 mL fill in 50 mL) | NDC 54643-5653-0 |
| One Vial 2 (10 mL) | NDC 54643-5655-0 |

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 and 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°C to 8° C (36°F 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.

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*For current labeling information, please visit https://www.fda.gov/drugsatfda*

- 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 for
**Sandoz Inc.**, Princeton, NJ 08540

Distributed by
**Baxter Healthcare Corporation**
Deerfield, IL 60015 USA

**INFUVITE** is a registered trademark of **Sandoz Canada Inc.**

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## HIGHLIGHTS OF PRESCRIBING INFORMATION

**These highlights do not include all the information needed to use INFUVITE ADULT safely and effectively. See full prescribing information for INFUVITE ADULT**

**INFUVITE ADULT (multiple vitamins injection), for intravenous use**
**Initial U.S. Approval: 2003**

### ---------- INDICATIONS AND USAGE ----------

INFUVITE ADULT is a combination of vitamins indicated for prevention of vitamin deficiency in adults and children aged 11 and older receiving parenteral nutrition (1)

### ---------- DOSAGE AND ADMINISTRATION ----------

- INFUVITE ADULT 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 ADULT is for administration by intravenous infusion after dilution (2.1)
- Recommended daily dosage is 10 mL (2.1)
- INFUVITE ADULT is supplied as a single dose and as a pharmacy bulk package.
  - **Single Dose**: Add one daily dose of 10 mL (5 mL from Vial 1 and 5 mL from Vial 2) to not less than 500 mL, and preferably 1000 mL, of intravenous dextrose, saline or similar infusion solutions. (2.2)
  - **Pharmacy Bulk Package**: Add the contents of Vial 1 to the contents of Vial 2. This provides ten 10 mL daily doses. Take 10 mL from Vial 2 and add to not less than 500 mL, and preferably 1000 mL, of intravenous dextrose, saline or similar infusion solutions. (2.2)
- After dilution in an intravenous infusion, refrigerate resulting solution unless used immediately. Use solution within 24 hours after dilution (2.2)
- Monitor blood vitamin concentrations (2.3)
- See Full Prescribing Information for drug incompatibilities (2.4)

### ---------- DOSAGE FORMS AND STRENGTHS ----------

- INFUVITE ADULT supplied as single dose is an injection consisting of two vials labeled Vial 1 (5 mL) and Vial 2 (5 mL) (3)
- INFUVITE ADULT supplied as a pharmacy bulk package is an injection consisting of two vials labeled Vial 1 (50 mL) and Vial 2 (50 mL fill in 100 mL Vial) (3)

### ---------- CONTRAINDICATIONS ----------

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

### ---------- WARNINGS AND PRECAUTIONS ----------

- *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)

### ---------- ADVERSE REACTIONS ----------

Adverse reactions have included anaphylaxis and anaphylactoid reactions including shortness of breath, wheezing and angioedema, 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.**

### ---------- DRUG INTERACTIONS ----------

Effect of INFUVITE ADULT 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 ADULT:

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

### ---------- USE IN SPECIFIC POPULATIONS ----------

- *Pregnancy and Lactation*: Pregnant and lactating patients should follow the U.S. Recommended Daily Allowances for their condition, because their vitamin requirements may exceed those of nonpregnant and nonlactating patients (8.1, 8.2)
- *Renal Impairment:* Monitor renal function, calcium, phosphorus and vitamin A levels in patients with renal impairment (8.6)
- *Hepatic Impairment:* Monitor vitamin A level in patients with liver disease, high alcohol consumption (8.7)

**See 17 for PATIENT COUNSELING INFORMATION**

**Revised: 11/2024**

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For current labeling information, please visit https://www.fda.gov/drugsatfda

FULL PRESCRIBING INFORMATION: CONTENTS*



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

## FULL PRESCRIBING INFORMATION

# 1 INDICATIONS AND USAGE

INFUVITE ADULT is a combination of vitamins indicated for the prevention of vitamin deficiency in adults and children 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 Instructions

INFUVITE ADULT is a combination product that contains the following vitamins: ascorbic acid, vitamin A, vitamin D, thiamine, riboflavin, pyridoxine, niacinamide, dexpanthenol, vitamin E, vitamin $K_1$, folic acid, biotin, and vitamin $B_{12}$.

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

INFUVITE ADULT **Single Dose:**

- Provides one daily dose of 10 mL (5 mL of Vial 1 plus 5 mL of Vial 2) which must be diluted prior to intravenous administration *[see Dosage and Administration (2.2)]*.

INFUVITE ADULT **Pharmacy Bulk Package:**

- Provides ten 10 mL daily doses when the content of vial 1 is transferred into the content of vial 2. One 10 mL dose is then added directly to intravenous fluid. Pharmacy bulk package of INFUVITE 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 (2.2)]*.

Patients with multiple vitamin deficiencies or with increased vitamin requirements may need multiple daily dosages as indicated. Some patients do not maintain adequate levels of certain vitamins when this formulation in recommended amounts is the only source of vitamins.

## 2.2 Preparation and Administration Instructions

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

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INFUVITE ADULT **Single Dose**:

- Use only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).
- Add 5 mL of Vial 1 and 5 mL of Vial 2 to at least 500 mL to 1000 mL, of intravenous dextrose or saline solutions.
- Discard unused portion.
- Visually inspect for particulate matter and discoloration prior to administration.
- After INFUVITE 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 INFUVITE ADULT, particularly A, D and riboflavin, are light sensitive.

INFUVITE ADULT **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 1 into the contents of Vial 2 to provide ten 10 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.
- One daily 10 mL dose should be added directly to at least 500 mL to 1000 mL, of intravenous dextrose, saline or similar infusion solutions.
- After INFUVITE 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 INFUVITE ADULT, particularly A, D and riboflavin, are light sensitive.

### 2.3 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.

### 2.4 Drug Incompatibilities

- INFUVITE 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, 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 ADULT may react with bisulfite solutions such as sodium bisulfite or vitamin K bisulfate.
- Do not add INFUVITE ADULT 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 ADULT **Single Dose:** is an injection for intravenous administration consisting of two vials labeled Vial 1 (5 mL) and Vial 2 (5 mL). For the vitamin strengths *[see Description (11)]*.

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INFUVITE ADULT **Pharmacy Bulk Package**: is an injection for intravenous administration consisting of two vials labeled Vial 1 (50 mL) and Vial 2 (50 mL Fill in 100 mL Vial). The mixed solution (100 mL) will provide ten 10 mL single doses. For the vitamin strengths *[see Description (11)]*.

**Vial 1 (Single Dose and Pharmacy Bulk Package)** is supplied as clear, yellow to orange liquid in amber glass vial closed with a rubber stopper, clear aluminum seal and a white flip-off.

**Vial 2 (Single Dose and Pharmacy Bulk Package)** is supplied as clear, colorless to pale yellow liquid in amber glass vial closed with a rubber stopper, clear aluminum seal and a deep purple flip-off.

# 4 CONTRAINDICATIONS

INFUVITE ADULT is contraindicated in patients who have

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

# 5 WARNINGS AND PRECAUTIONS

## 5.1 Aluminum Toxicity

INFUVITE ADULT contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate 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 ADULT in patients with renal impairment.

## 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 ADULT. There have been rare reports of anaphylactoid reactions following intravenous doses of thiamine. No fatal anaphylactoid reactions associated with INFUVITE ADULT have 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 ADULT, should be undertaken with caution *[see Use in Specific Populations (8.6 and 8.7)]*.

## 5.4 Decreased Anticoagulant Effect of Warfarin

INFUVITE ADULT contains Vitamin K, which may decrease the anticoagulant action of warfarin. In patients who are on warfarin anticoagulant therapy receiving INFUVITE ADULT 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 ADULT 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 ADULT in patients with suspected

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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 ADULT, blood concentration should be periodically monitored to determine if deficiencies or excesses are developing. INFUVITE ADULT may not correct long-standing specific vitamin deficiencies. The administration of additional therapeutic doses of specific vitamins may be required *[see Dosage and Administration (2.3)]*.

### 5.7 Interference with Urine Glucose Testing

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

## 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 (5.2)]*
- Hypervitaminosis A *[see Warnings and Precautions (5.3)]*

The following adverse reactions have been identified during postapproval use of INFUVITE 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, 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 ADULT, antagonizes the anticoagulant action of warfarin. In patients who are co-administered warfarin and INFUVITE ADULT, 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.

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### 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.

Chloramphenicol: In patients with pernicious anemia, the hematologic response to vitamin $B_{12}$ therapy may be inhibited by chloramphenicol.

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

Risk Summary
Administration of the approved recommended dose of INFUVITE ADULT in parental nutrition is not expected to cause major birth defects, miscarriage, or adverse maternal or fetal outcomes. Pregnant patients should follow the U.S. Recommended Daily Allowances for pregnancy because their vitamin requirements may exceed those of nonpregnant patients. Deficiency of essential vitamins may result in adverse pregnancy outcomes *(see Clinical Considerations).* Animal reproduction studies have not been conducted with INFUVITE ADULT.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Clinical Considerations
*Disease-associated Maternal and/or Embryo-Fetal Risk*
Deficiency of essential vitamins has been associated with adverse pregnancy and fetal outcomes, such as maternal folic acid deficiency and an increased risk of neural tube defects. Therefore, parenteral nutrition with multiple vitamins injection should be considered if a pregnant woman's nutritional requirements cannot be fulfilled by oral or enteral intake.

### 8.2 Lactation

Risk Summary
Multiple vitamins present in INFUVITE ADULT are also present in human milk. Administration of the approved recommended dose of INFUVITE ADULT In parental nutrition is not expected to cause harm to a breastfed infant. There is no information on the effects of INFUVITE ADULT on milk production. Lactating patients should follow the U.S. Recommended Daily Allowances for their condition, because their vitamin requirements may exceed those of nonlactating patients. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for INFUVITE ADULT and any potential adverse effects on the breastfed child from INFUVITE ADULT or from the underlying maternal condition.

### 8.4 Pediatric Use

Safety and effectiveness in children below the age of 11 years have not been established.

### 8.5 Geriatric Use

Safety and effectiveness for geriatric use have not been established.

### 8.6 Renal Impairment

INFUVITE 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 (5.1 and 5.3)].*

### 8.7 Hepatic Impairment

INFUVITE ADULT has not been studied in patients with liver impairments. Monitor vitamin A level in patients with liver disease, high alcohol consumption *[see Warnings and Precautions (5.3)].*

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For current labeling information, please visit https://www.fda.gov/drugsatfda

# 10 OVERDOSAGE

Signs and symptoms of acute or chronic overdosage may be those of individual INFUVITE ADULT component toxicity. In post-marketed surveillance, overdosage with INFUVITE ADULT at two times the prescribed dose did not result in toxicity.

# 11 DESCRIPTION

INFUVITE ADULT (multiple vitamins injection) is a sterile product consisting of two vials provided as a single dose or as a pharmacy bulk package, both intended for intravenous use for administration by intravenous infusion after dilution:

INFUVITE ADULT **Single Dose** - two 5 mL single-dose vials labeled Vial 1 and Vial 2.

INFUVITE ADULT **Pharmacy Bulk Package** - two vials – 1 each of Vial 1 (50 mL) and Vial 2 (50 mL Fill in 100 mL Vial). The mixed solution (100 mL) will provide ten 10 mL single doses.

**Each 5 mL of Vial 1 contains:**

| | |
|---|---|
| Ascorbic acid (Vitamin C) | 200 mg |
| Vitamin A* (as palmitate) | 3,300 IU |
| Vitamin $D_3$* (cholecalciferol) | 200 IU |
| Thiamine (Vitamin $B_1$) (as the hydrochloride) | 6 mg |
| Riboflavin (Vitamin $B_2$) (as riboflavin 5-phosphate sodium) | 3.6 mg |
| Pyridoxine HCl (Vitamin $B_6$) | 6 mg |
| Niacinamide | 40 mg |
| Dexpanthenol (as *d*-pantothenyl alcohol) | 15 mg |
| Vitamin E* (*dl*-α-tocopheryl acetate) | 10 IU |
| Vitamin $K_1$* | 150 mcg |

*Polysorbate 80 is used to water solubilize the oil-soluble vitamins A, D, E, and K.

Inactive ingredients: 1.4% polysorbate 80, sodium hydroxide and/or hydrochloric acid for pH adjustment, and water for injection.

**Each 5 mL of Vial 2 contains:**

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

Inactive ingredients: 30% propylene glycol, citric acid and/or sodium citrate for pH adjustment, and water for injection.

INFUVITE ADULT makes available a combination of important 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.

Contains no more than 70 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 ADULT.

# 16 HOW SUPPLIED/STORAGE AND HANDLING

**How Supplied**

This label may not be the latest approved by FDA.
For current labeling information, please visit https://www.fda.gov/drugsatfda

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

**Vial 1 (Single Dose and Pharmacy Bulk Package)** is supplied as clear, yellow to orange liquid in amber glass vial closed with a rubber stopper, clear aluminum seal and a white flip-off.

**Vial 2 (Single Dose and Pharmacy Bulk Package)** is supplied as clear, colorless to pale yellow liquid in amber glass vial closed with a rubber stopper, clear aluminum seal and a deep purple flip-off.

INFUVITE ADULT **Single Dose**:

| | |
|---|---|
| Carton contains total ten single-dose vials | NDC 54643-5649-1 |
| Five of Vial 1 (5 mL) | NDC 54643-5657-1 |
| Five of Vial 2 (5 mL) | NDC 54643-5659-1 |

one Vial 1 plus one Vial 2 to be used for a single dose *[see Dosage and Administration (2.1)]*.

INFUVITE ADULT **Pharmacy Bulk Package:**

| | |
|---|---|
| Carton contains total two vials | NDC 54643-5650-2 |
| One Vial 1 (50 mL) | NDC 54643-5661-2 |
| One Vial 2 (50 mL Fill in 100 mL Vial) | NDC 54643-5663-2 |

Mix contents of Vial 1 with Vial 2 to provide 10 single doses *[see Dosage and Administration (2.1)]*.

**Storage and Handling**

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

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

# 17 PATIENT COUNSELING INFORMATION

Instruct patients (if age appropriate) and caregivers:

- 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 ADULT.
- 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 such as rash, erythema, pruritus, headache, dizziness, agitation, anxiety, and diplopia.
- That the patients on warfarin anticoagulant therapy will be monitored periodically with blood prothrombin/ INR levels to determine if their 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 ADULT 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 ADULT may cause false negative urine glucose results.

Manufactured for
**Sandoz Inc.**, Princeton, NJ 08540

Distributed by
**Baxter Healthcare Corporation**

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Deerfield, IL 60015 USA

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NDC 54643-5647-0

Rx Only

# INFUVITE® *PEDiatric*

(multiple vitamins injection)

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

**Contents:**
One Vial 1 (40 mL fill in 50 mL Vial) and
One Vial 2 (10 mL).
Both vials combined produce 10 single doses. Discard Unused Portion

Baxter

PRESS

NDC 54643-5647-0

Rx Only
Sterile

**Transfer the contents of Vial 2 into Vial 1 to provide ten 5 mL single doses. Each 5 mL single dose should be added to not less than 100 mL of infusion fluid.**

Once closure system has been compromised, withdrawal of container contents should be completed within 4 hours.

**Recommended Dosage:**
See prescribing information.

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

**Preservative-Free**
Contains no more than 30 mcg/L of aluminum (combined Vials 1 and 2).

# INFUVITE® *PEDiatric*

(multiple vitamins injection)

**PHARMACY BULK PACKAGE
NOT FOR DIRECT INFUSION**

**Contents:**
One Vial 1 (40 mL fill in 50 mL Vial). and
One Vial 2 (10 mL).
Both vials combined produce 10 single doses.
Discard Unused Portion
For Intravenous Infusion
**Must be diluted before use.**

Baxter

Manufactured for
**Sandoz Inc.**
Princeton, NJ 08540

Distributed by
**Baxter Healthcare Corporation**
Deerfield, IL 60015 USA

Product of Canada

**INFUVITE** is a registered trademark of **Sandoz Canada Inc.**

Rev. 10/2024 XXXXXXXX
2A9061

3 54643 56470 3

Area for Serialization
(Printed online during packaging)

**Each 4 mL of Vial 1 contains:**

| | |
|---|---|
| Vitamin C | 80 mg |
| Vitamin A | 2,300 IU |
| Vitamin $D_3$ | 400 IU |
| Thiamine ($B_1$) | 1.2 mg |
| Riboflavin ($B_2$) | 1.4 mg |
| Pyridoxine HCL ($B_6$) | 1 mg |
| Niacinamide | 17 mg |
| Dexpanthenol | 5 mg |
| Vitamin E (*dl*-α-tocopheryl acetate) | 7 IU |
| Vitamin $K_1$ | 0.2 mg |

with 50 mg polysorbate 80, sodium hydroxide and/or hydrochloric acid for pH adjustment, and water for injection.

**Each 1 mL of Vial 2 contains:**

| | |
|---|---|
| Folic Acid | 140 mcg |
| Biotin | 20 mcg |
| Cyanocobalamin ($B_{12}$) | 1 mcg |

with 75 mg mannitol, citric acid and/or sodium citrate for pH adjustment and water for injection.

(b) (4)

*This label may not be the latest approved by FDA.*
*For current labeling information, please visit https://www.fda.gov/drugsatfda*

NDC 54643-5653-0 Rx Only

# INFUVITE® *PEDiatric*

(multiple vitamins injection)

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

**Vial 1** Sterile

For Intravenous Infusion

**Must be diluted before use.**

Baxter **40 mL** (fill in 50 mL vial)

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

**Recommended Dosage:** See prescribing information. Discard Unused Portion.

**Transfer the contents of Vial 2 into Vial 1 to provide ten 5 mL single doses. Each single-dose should be added to at least 100 mL of infusion fluid.**

*Contains no more than 30 mcg/L of aluminum (combined Vials 1 and 2).*

Once closure system has been compromised, withdrawal of container contents should be completed within 4 hours.

Distributed by: Baxter Healthcare Corporation, Deerfield, IL 60015 USA Rev. 10/2024

Entered: Date Time

(01)00354643565304

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LOT:

EXP: YYYYMMM

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For current labeling information, please visit https://www.fda.gov/drugsatfda

NDC 54643-5655-0 Rx Only

**INFUVITE® *PEDiatric***

(multiple vitamins injection)

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

**Vial 2** Sterile

For Intravenous Infusion
**Must be diluted before use.**

Baxter **10 mL**

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

**Recommended Dosage:** See prescribing information. Discard Unused Portion.

**Transfer the contents of Vial 2 into Vial 1.**

*Contains no more than 30 mcg/L of aluminum (combined Vials 1 and 2).*

Dist. by: Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Rev. 10/2024

(01)00354643565502

LOT:
EXP: YYYYMMM

(b) (4)

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For current labeling information, please visit https://www.fda.gov/drugsatfda

NDC 54643-5646-1

Rx Only

# INFUVITE® *PEDiatric*

## (multiple vitamins injection)

**Contents:**
Five of Vial 1 (4 mL) and
Five of Vial 2 (1 mL).

Sterile
For Intravenous Infusion
**Must be diluted before use.**

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

**Baxter**

Manufactured for **Sandoz Inc.**, Princeton, NJ 08540

Distributed by **Baxter Healthcare Corporation** Deerfield, IL 60015 USA

Product of Canada

**INFUVITE** is a registered trademark of **Sandoz Canada Inc.**

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Rev. 10/2024

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N 3 54643-5646-1 1

**Preservative-Free**
Contains no more than 30 mcg/L of aluminum (combined Vials 1 and 2).

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

**The contents of both vials should be added to not less than 100 mL of infusion fluid.**

**Recommended Dosage:**
See prescribing information.

Area for Serialization
(Printed online during packaging)

**Each 4 mL of Vial 1 contains:**

| | |
|---|---|
| Vitamin C | 80 mg |
| Vitamin A | 2,300 IU |
| Vitamin $D_3$ | 400 IU |
| Thiamine ($B_1$) | 1.2 mg |
| Riboflavin ($B_2$) | 1.4 mg |
| Pyridoxine HCl ($B_6$) | 1 mg |
| Niacinamide | 17 mg |
| Dexpanthenol | 5 mg |
| Vitamin E (*dl-α-tocopheryl acetate*) | 7 IU |
| Vitamin $K_1$ | 0.2 mg |

With 75 mg mannitol, citric acid and/or sodium citrate for pH adjustment and water for injection.

**Each 1 mL of Vial 2 contains:**

| | |
|---|---|
| Folic acid | 140 mcg |
| Biotin | 20 mcg |
| Cyanocobalamin ($B_{12}$) | 1 mcg |

With 50 mg polysorbate 80, sodium hydroxide and/or hydrochloric acid for pH adjustment, and water for injection.

NDC 54643-5646-1

Rx Only

INFUVITE® *PEDiatric*

(multiple vitamins injection)

**Contents:**
Five of Vial 1 (4 mL) and
Five of Vial 2 (1 mL).

Sterile
For Intravenous Infusion
**Must be diluted before use.**

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

**Baxter**

(b) (4)

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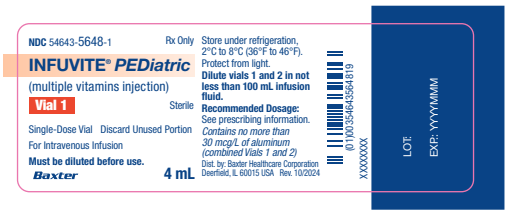


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NDC 54643-5661-2 Rx Only

# INFUVITE® ADULT

(multiple vitamins injection)

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

**Vial 1** Sterile

For Intravenous Infusion
**Must be diluted before use.**

Baxter

**50 mL**

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

**Recommended Dosage:** See prescribing information. Discard Unused Portion.

**Transfer the contents of Vial 1 into Vial 2 to provide ten 10 mL single doses. Each 10 mL single dose should be added to not less than 500 mL of infusion fluid.**

*Contains no more than 70 mcg/L of aluminum (combined Vials 1 and 2).*

Distributed by: Baxter Healthcare Corporation
Deerfield, IL 60015 USA Rev. 10/2024

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EXP: YYYYMMM

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NDC 54643-5663-2 Rx Only

# INFUVITE® ADULT
(multiple vitamins injection)

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

**Vial 2** Sterile

For Intravenous Infusion

**Must be diluted before use.**

**50 mL** (fill in 100 mL vial)

Baxter

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

**Recommended Dosage:** See prescribing information. Discard Unused Portion.

**Transfer the contents of Vial 1 into Vial 2 to provide ten 10 mL single doses. Each 10 mL single dose should be added to not less than 500 mL of infusion fluid.**

*Contains no more than 70 mcg/L of aluminum (combined Vials 1 and 2).*

Once closure system has been compromised, withdrawal of container contents should be completed within 4 hours.

Distributed by: Baxter Healthcare Corporation
Deerfield, IL 60015 USA Rev. 10/2024

Entered: Date _____ Time _____

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LOT:

EXP: YYYYMMM

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Reference ID: 5474648

NDC 54643-5650-2

# INFUVITE® ADULT

(multiple vitamins injection)

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

**Each 5 mL of Vial 1 contains:**

| | |
|---|---|
| Vitamin C | 200 mg |
| Vitamin A | 3,300 IU |
| Vitamin $D_3$ | 200 IU |
| Thiamine ($B_1$) | 6 mg |
| Riboflavin ($B_2$) | 3.6 mg |
| Pyridoxine HCL ($B_6$) | 6 mg |
| Niacinamide | 40 mg |
| Dexpanthenol | 15 mg |
| Vitamin E (*dl*-α-tocopheryl acetate) | 10 IU |
| Vitamin $K_1$ | 150 mcg |

with 1.4% polysorbate 80, sodium hydroxide and/or hydrochloric acid for pH adjustment, and water for injection.

**Each 5 mL of Vial 2 contains:**

| | |
|---|---|
| Folic Acid | 600 mcg |
| Biotin | 60 mcg |
| Cyanocobalamin ($B_{12}$) | 5 mcg |

with 30% propylene glycol, citric acid and/or sodium citrate for pH adjustment, and water for injection.

Area for Serialization
(Printed online during packaging)

**Transfer the contents of Vial 1 into Vial 2 to provide ten 10 mL single doses. Each 10 mL single dose should be added to not less than 500 mL of infusion fluid.**

Once closure system has been compromised, withdrawal of container contents should be completed within 4 hours.

**Recommended Dosage:**
See prescribing information.

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

**Preservative-Free**
Contains no more than 70 mcg/L of aluminum (combined Vials 1 and 2).

Baxter

**Must be diluted before use.**

For Intravenous Infusion

Both vials combined produce 10 single doses.
Discard Unused Portion

**Contents:**
One Vial 1 (50 mL) and
One Vial 2 (50 mL fill in 100 mL Vial).

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

(multiple vitamins injection)

**INFUVITE® ADULT**

NDC 54643-5650-2 Rx Only
Sterile

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Baxter

Both vials combined produce 10 single doses. Discard Unused Portion.

**Contents:**
One Vial 1 (50 mL) and
One Vial 2 (50 mL fill in 100 mL Vial).

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

(multiple vitamins injection)

**INFUVITE® ADULT**

NDC 54643-5650-2 Rx Only

Manufactured for
**Sandoz Inc.**, Princeton, NJ 08540

Distributed by
**Baxter Healthcare Corporation**
Deerfield, IL 60015 USA

Product of Canada

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Rev. 10/2024 XXXXXXXX

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NDC 54643-5649-1

Rx Only
Sterile

# INFUVITE® ADULT
(multiple vitamins injection)

**Contents:**
Five of Vial 1 (5 mL) and
Five of Vial 2 (5 mL).

For Intravenous Infusion
**Must be diluted before use.**

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

Baxter

Manufactured for
**Sandoz Inc.**, Princeton, NJ 08540

Distributed by
**Baxter Healthcare Corporation**
Deerfield, IL 60015 USA

Product of Canada

**INFUVITE** is a registered trademark of
**Sandoz Canada Inc.**

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Rev. 10/2024

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**Preservative-Free**
Contains no more than 70 mcg/L of aluminum (combined Vials 1 and 2).

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

**Recommended Dosage:**
See prescribing information.

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

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

Area for Serialization
(Printed online during packaging)

**Each 5 mL of Vial 1 contains:**

| | |
|---|---|
| Vitamin C | 200 mg |
| Vitamin A | 3,300 IU |
| Vitamin $D_3$ | 200 IU |
| Thiamine ($B_1$) | 6 mg |
| Riboflavin ($B_2$) | 3.6 mg |
| Pyridoxine HCL ($B_6$) | 6 mg |
| Niacinamide | 40 mg |
| Dexpanthenol | 15 mg |
| Vitamin E (*dl*-α-tocopheryl acetate) | 10 IU |
| Vitamin $K_1$ | 150 mcg |

**Each 5 mL of Vial 2 contains:**

| | |
|---|---|
| Folic Acid | 600 mcg |
| Biotin | 60 mcg |
| Cyanocobalamin ($B_{12}$) | 5 mcg |

With 1.4% polysorbate 80, sodium hydroxide and/or hydrochloric acid for pH adjustment, and water for injection.

with 30% propylene glycol, citric acid and/or sodium citrate for pH adjustment and water for injection.

NDC 54643-5649-1

Rx Only
Sterile

INFUVITE® ADULT
(multiple vitamins injection)

**Contents:**
Five of Vial 1 (5 mL) and
Five of Vial 2 (5 mL).

For Intravenous Infusion
**Must be diluted before use.**

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

Baxter

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MARINA ZEMSKOVA
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