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

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)]*.

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

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.

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

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.

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.

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.

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.

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.

- 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.

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