INFUVITE

Multiple Vitamins for Infusion


See inside for Indications and Important Risk Information.
A.S.P.E.N. suggests clinicians purchase product with the lowest aluminum content when possible.¹

- Not more than 30 mcg/L for INFUVITE PEDIatric.
- Not more than 70 mcg/L for INFUVITE ADULT.
  (combined vials 1 and 2)

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

Full portfolio of injectable multivitamin formulations.

- The only preservative-free option available.
- The only pediatric pharmacy bulk package available.
- Ready-to-use liquid formulas. Does not require reconstitution.
- Latex free.

Supplied in both single-dose and pharmacy bulk package configurations.

- Adult and pediatric formulas available in convenient single-dose configurations.
- Pharmacy bulk packages are well suited for use in high-volume pharmacy admixture programs, which allow you to:
  - Prepare up to 10 doses at once.
  - Reduce the number of physical manipulations, thereby helping to reduce the potential risk of contamination and improve compounding efficiency.
- Pharmacy bulk package is not for direct infusion.
- Consistent intake of vitamin K is recommended for patients on anticoagulation therapy.
  - INFUVITE ADULT Multiple Vitamins for Infusion provide a consistent daily supply of vitamin K for these patients.
  - Vitamin K is essential for the activation of vitamin-K dependent proteins, which are involved not only in blood coagulation but in bone metabolism and inhibition of arterial calcification.²

Options deliver flexibility and simplicity.

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Indications:

- **INFUVITE** Multiple Vitamins for Infusion are for intravenous infusion after dilution only.

- **INFUVITE** ADULT Multiple Vitamins for Infusion are indicated as a daily multivitamin maintenance supplement for adults and children aged 11 and older receiving parenteral nutrition.

- **INFUVITE** PEdiatric Multiple Vitamins for Infusion are indicated as a daily multivitamin maintenance dosage for infants and children up to 11 years of age receiving parenteral nutrition.

Important Risk Information:

- **INFUVITE** Multiple Vitamins for Infusion are contraindicated where there is a pre-existing hypervitaminosis or known hyper-sensitivity to any of the vitamins or excipients in the product.

- Allergic reactions have been known to occur following intravenous administration of thiamine and vitamin K. The formulation is contraindicated prior to blood sampling for detection of megaloblastic anemia.

- Caution should be exercised when administering **INFUVITE** Multiple Vitamins for Infusion to patients on warfarin sodium-type anticoagulation therapy. Periodic monitoring of prothrombin time/INR response is essential in determining the appropriate dosage of anticoagulant therapy.

- If this formulation is the only source of vitamins for a long period of time, blood concentrations of each of the vitamins should be monitored, particularly vitamins A, C, D, and folic acid, to determine if deficiencies are occurring.

- There have been rare reports of anaphylactoid reactions following parenteral multivitamin administration. Rare reports of anaphylactoid reactions have also been reported following large intravenous doses of thiamine. However, the risk is negligible if thiamine is coadministered with other vitamins in the B group.

- **INFUVITE** Multiple Vitamins for Infusion contain aluminum that may be toxic.

- See enclosed for complete prescribing information.

Reference
Move Ahead

*with streamlined parental nutrition.*

With our 70-plus years in developing solutions that work together to improve patient outcomes, Baxter offers you the broadest portfolio of parenteral nutrition products and technologies available.

Our complete line includes premix formulations, injectable multiple vitamins, compounding solutions and technologies, micronutrients, and ongoing support. More options mean that you can efficiently meet the nutritional needs of each and every patient.

For more information on INFUVITE Multiple Vitamins for Infusion or our other nutrition products, please contact your local Baxter representative. To order product, please call the Baxter Center for Service at 1-888-229-0001.
INFUVITE Pediatric

Multiple Vitamins for Infusion

Rx only

For intravenous infusion after dilution only.

Pharmacy Bulk Package Not for Direct Injection

Description

INFUVITE Pediatric is a pharmacy bulk package containing multiple vitamins for infusion.

Indications and Usage

INFUVITE Pediatric is indicated for use in maintaining and supplementing the dietary intake of patients who are prone to vitamin deficiencies. INFUVITE Pediatric may be given on an as needed basis and for a specified length of time, as determined by the attending physician.

Contraindications

INFUVITE Pediatric should not be used in patients who are hypersensitive to any of the components of the formulation.

Warnings

INFUVITE Pediatric is contraindicated in patients with known allergies or sensitivity to any component of the formulation.

Precautions

INFUVITE Pediatric is not recommended for use in patients with acid-base abnormalities or electrolyte imbalances unless they have first been corrected.

Adverse Reactions

INFUVITE Pediatric may cause adverse reactions such as fever, chills, nausea, vomiting, and diarrhea.

Dose and Administration

INFUVITE Pediatric is administered as a 10 mL dose of Vial 1 (2.6 mL) and a 0.65 mL dose of Vial 2 (0.65 mL) for a total of 10.65 mL per daily dose.

Directions for Dispensing

INFUVITE Pediatric is dispensed as a pharmacy bulk package and is not for direct injection.

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Vitamin B12 (cyanocobalamin) ............................................. 1 mcg
Folic acid ........................................................................ 140 mcg
Polyisorbate 80 is used to water solubilize the oil-soluble
Vitamin K1* .................................................................................. 0.2 mg
sole source of vitamins for long periods of time.
INFUVITE Pediatric

For intravenous infusion after dilution only.

INFUVITE Pediatric

Multiple vitamins for infusion

Rx only

For intravenous infusion after dilution only.

Pharmacy Bulk Package Not for Direct Injection

Description

INFUVITE Pediatric is a pharmacy bulk package containing multiple vitamins for infusion.

Indications and Usage

INFUVITE Pediatric is indicated for use in maintaining and supplementing the dietary intake of patients who are prone to vitamin deficiencies. INFUVITE Pediatric may be given on an as needed basis and for a specified length of time, as determined by the attending physician.

Contraindications

INFUVITE Pediatric should not be used in patients who are hypersensitive to any of the components of the formulation.

Warnings

INFUVITE Pediatric is contraindicated in patients with known allergies or sensitivity to any component of the formulation.

Precautions

INFUVITE Pediatric is not recommended for use in patients with acid-base abnormalities or electrolyte imbalances unless they have first been corrected.

Adverse Reactions

INFUVITE Pediatric may cause adverse reactions such as fever, chills, nausea, vomiting, and diarrhea.

Dose and Administration

INFUVITE Pediatric is administered as a 10 mL dose of Vial 1 (2.6 mL) and a 0.65 mL dose of Vial 2 (0.65 mL) for a total of 10.65 mL per daily dose.

Directions for Dispensing

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**INFUVITE® ADULT**

**PHARMACY BULK PACKAGE**

**Multiple Vitamins for Infusion**

Rx Only

For intravenous infusion after dilution only.

**Pharmacy Bulk Package Not for Direct Infusion**

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**Description**

INFUVITE ADULT (PHARMACY BULK PACKAGE) is a sterile product consisting of 2 vials – 1 each of Vial 1 (50 mL) and Vial 2 (50 mL, Fill in 100 mL Vial), provided as a pharmacy bulk package.

A pharmacy bulk package is a container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for intravenous infusion.

Each 5 mL of Vial 1 contains:

- Ascorbic acid (Vitamin C) .............. 200 mg
- Vitamin A* (as palmitate) ............. 3,300 IU
- Vitamin D3 (cholecalciferol) ........ 200 IU
- Thiamine (Vitamin B1) (as the hydrochloride) ........... 6 mg
- Riboflavin (Vitamin B2) (as riboflavin 5-phosphate sodium) ........ 3.6 mg
- Pyridoxine HCl (Vitamin B6) ........ 6 mg
- Niacinamide .................. 40 mg
- Desipramine .................... 15 mg
- Vitamin E* (as DL-tocopheryl acetate) ........... 10 IU
- Vitamin K1* ................. 150 mcg

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

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

Each 5 mL of Vial 2 contains:

- Folic acid .................. 600 mcg
- Biotin .................. 60 mcg
- Vitamin B12 (cyanocobalamin) ........ 5 mcg

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

*Aqueous* multiple vitamin preparation for intravenous infusion:

INFUVITE ADULT (PHARMACY BULK PACKAGE) Multiple Vitamins for Infusion 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 fill, permitting intravenous administration of these vitamins.

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

**Indications and Usage**

INFUVITE ADULT (PHARMACY BULK PACKAGE) is indicated as a daily multivitamin maintenance supplement for adults and children aged 11 and older receiving parenteral nutrition.

INFUVITE ADULT (PHARMACY BULK PACKAGE) is also indicated in situations where administration by the intravenous route is required. Such situations include surgery, extensive burns, fractures and other trauma, serious infectious disease, and convalescent states, which may provoke a "stress" situation with profound alterations in the body’s metabolic demands and consequent tissue depletion of nutrients.

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

INFUVITE ADULT (PHARMACY BULK PACKAGE) administered in intravenous fluids under proper dilution contributes intake of necessary vitamins toward maintaining the body’s normal resistance and repair processes.

Patients with multiple vitamin deficiencies or with markedly increased requirements may be given multiples of the daily dosage for two or more days, as indicated by the clinical status.

Some patients do not maintain adequate levels of certain vitamins when a multiple vitamin infusion is given over a long period of time, blood vitamin concentrations should be monitored to ensure maintenance of adequate levels. If deficiencies appear to be developing, multiples of the formulation (1.5 to 3 times) may be needed for a period of time. When multiples of the formulation are used for more than a few weeks, vitamins A and D should be monitored occasionally to be certain that an excess accumulation of these vitamins is not occurring.

**Contraindications**

INFUVITE ADULT (PHARMACY BULK PACKAGE) is contraindicated where there is a preexisting vitamin hyperresponsiveness, or a known hypersensitivity to any of the vitamins or excipients in the product.

Allergic reactions have been known to occur following intravenous administration of thiamine and vitamin K. The formulation is contraindicated prior to blood sampling for detection of megaloblastic anemia, as the folic acid and the cyanocobalamin in the vitamin solution can mask serum deficits.

**Warnings**

This product 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 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.

**Precautions**

If this formulation is the only source of vitamins for long periods of time, blood concentration of each of the vitamins should be monitored, particularly vitamins A, D, E, and folic acid, to determine if deficiencies are occurring. If deficiencies are developing or when long-standing vitamin deficiencies are present, it may be necessary to add therapeutic amounts of certain vitamins to supplement the maintenance vitamin provided in INFUVITE ADULT (PHARMACY BULK PACKAGE).

**Drug – Drug/Solution Interactions:**

**Cautions should be exercised when administering INFUVITE ADULT (PHARMACY BULK PACKAGE) to patients on warfarin sodium-type anticoagulant therapy. In such patients, vitamin K may antagonize the hypoprothrombinemic response to anticoagulant drugs, such as warfarin and its congeners. Therefore, periodic monitoring of prothrombin/INR response is essential in determining the appropriate dosage of anticoagulant therapy.**

INFUVITE ADULT (PHARMACY BULK PACKAGE) (Multiple Vitamins for Infusion) is not physically compatible with alkaline solutions or moderately alkaline drugs such as aminoguanidine, chlorothiazide sodium, ampicillin or sodium bicarbonate.

Tetracycline HCl and ampicillin may not be physically compatible with INFUVITE ADULT (PHARMACY BULK PACKAGE). Also, it has been reported that folic acid is unstable in the presence of calcium salts such as calcium gluconate. Direct addition to intravenous fat emulsions is not recommended. Consult appropriate references for listings of possible compatibility of solutions and drugs with the vitamin infusion. In such circumstances, admixture or Y-site administration of vitamin solutions should be avoided.

A number of interactions between vitamins and drugs have been reported which may affect the metabolism of either agent. The following are examples of these types of interactions.

Folic acid may lower the serum concentration of phenytoin resulting in increased sedation or seizure activity. Conversely, phenytoin may decrease serum folic acid concentrations and, therefore, should be avoided in pregnancy. Folic acid may decrease the patient’s response to methotrexate therapy.

Pyridoxine may decrease the efficacy of levodopa by increasing its metabolism. Concomitant administration of hydralazine or isoniazid may increase pyridoxine requirement.

In patients with pernicious anemia, the hematologic response to vitamin B12 therapy may be inhibited by concomitant administration of chlorpromazine.
Several vitamins have been reported to decrease the activity of certain antibiotics. Thiamine, riboflavin, pantothenate, niacinamide, and ascorbic acid have been reported to decrease the antibiotic activity of erythromycin, kanamycin, streptomycin, dihydrostreptomycin, and lincomycin. Bismuth is inactivated in vitro by ascorbic acid and riboflavin.

Vitamin K may antagonize the hypoprothrombinemic effect of oral anticoagulants (see dosed statement above). Consult appropriate references for additional specific vitamin-drug interactions.

Some of the vitamins in INFUVITE ADULT (PHARMACY BULK PACKAGE) may react with vitamin K bisulfite or sodium bisulfite; if bisulfite solutions are necessary, patients should be monitored for Vitamin A and d Thiamine deficiencies.

**Drug-Laboratory Test Interactions:**
Ascorbic acid in the urine may cause false negative urine glucose determinations. Carcinogenesis, Mutagenesis, and Impairment of Fertility: Carcinogenicity, mutagenicity, and fertility studies have not been performed with INFUVITE ADULT (PHARMACY BULK PACKAGE).

**Pregnancy:**
Pregnancy Category C:
Animal reproduction studies have not been conducted with INFUVITE ADULT (PHARMACY BULK PACKAGE) (Multiple Vitamins for Infusion). INFUVITE ADULT (PHARMACY BULK PACKAGE) should be given to a pregnant woman only if clearly needed. Pregnant women should follow the U.S. Recommended Daily Allowances for their condition, because their vitamin requirements may exceed those of nonpregnant women. The use of INFUVITE ADULT (PHARMACY BULK PACKAGE) has not been studied in human pregnancy.

Nursing Mothers: Lactating women should follow the U.S. Recommended Daily Allowances for their condition, because their vitamin requirements may exceed those of nonlactating women. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when INFUVITE ADULT (PHARMACY BULK PACKAGE) is administered to a nursing mother.

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

**Adverse Reactions:**
There have been rare reports of anaphylactic reactions following parenteral multivitamin administration. Rare reports of anaphylactoid reactions have also been reported following large intravenous doses of thiamine. However, the risk is negligible if thiamine is coadministered with other vitamins of the B group.

There have been rare reports of the following types of reactions:
- Dermatologic – rash, erythema, pruritis
- CNS – headache, dizziness, agitation, anxiety
- Gastrointestinal – diarrhea
- Allergic – urticaria, shortness of breath, wheezing and angioedema.

**Overdosage:**
The fat-soluble vitamins A, D, and E can accumulate to harmful levels. The possibility of hypercalcemia or D and riboflavin should be borne in mind. Clinical manifestations of vitamin D and riboflavin deficiency, therefore, exposure to light should be minimized.

Water-soluble vitamins are readily excreted in the urine. Treatment of vitamin overdosage usually consists of withdrawal of the vitamin.

**Dosage and Administration:**
INFUVITE ADULT (PHARMACY BULK PACKAGE) is ready for immediate use in adults and children aged 11 years and older when added to intravenous infusion fluids.

**INFUVITE ADULT (PHARMACY BULK PACKAGE) should not be given as a direct, undiluted intravenous injection as it may give rise to dizziness, faintness, and possible tissue irritation.**

Preparation of INFUVITE ADULT (PHARMACY BULK PACKAGE) for intravenous feeding should be done by transferring the contents of Vial 1 into the contents of Vial 2 to provide ten 10 mL single doses. One daily 10 mL dose should be added directly to not less than 500 mL, and preferably 1000 mL, of intravenous saline, dextrose, or other solutions. Discard any unused portion.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

After INFUVITE ADULT (PHARMACY BULK PACKAGE) is diluted in an intravenous infusion, the resulting solution should be refrigerated unless it is to be used immediately. The solution should be used within 24 hours after dilution. Some of the vitamins in this product, particularly A and D and riboflavin, are light sensitive; therefore, exposure to light should be minimized.

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

**INFUVITE ADULT (PHARMACY BULK PACKAGE) is a PHARMACY BULK PACKAGE. IT IS NOT INTENDED FOR DIRECT INFUSION. DISCARD UNUSED PORTION.**

**Directions For Dispensing From Pharmacy Bulk Vial**
The Pharmacy Bulk Vial is intended for single puncture, multiple dispensing and for intravenous use only. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion. The Pharmacy Bulk Package is to be used only in a suitable work area such as a laminar flow hood or an equivalent clean air compounding area. Dispensing from Pharmacy Bulk Vial should be completed as soon as possible after initial entry.

**How Supplied:**
INFUVITE ADULT (PHARMACY BULK PACKAGE) – NDC 54643-5660-2, is available in boxes containing 2 vials – 1 each of Vial 1 (50 mL) and Vial 2 (50 mL fill in 100 mL Vial). Mix contents of Vial 1 with Vial 2 to provide 10 single doses.

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

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