INFUVITE PEDIATRIC - multiple vitamins
Baxter Healthcare Corporation

For intravenous infusion after dilution only.

DESCRIPTION

INFUVITE Pediatric is a sterile product consisting of two vials: a 4 mL single-dose vial labeled Vial 1 and a 1 mL single-dose vial labeled Vial 2.

Each 4 mL of Vial 1 contains:
Ascorbic acid (Vitamin C) ..... 80 mg
Vitamin A[1] (as palmitate)..... 2,300 IU
Vitamin D_3[1] (cholecalciferol) ..... 400 IU
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[1] (dl-α-tocopheryl acetate)..... 7 IU
Vitamin K_1[1]..... 0.2 mg
Inactive ingredients: 50 mg polysorbate 80, sodium hydroxide and/or hydrochloric acid for pH adjustment and water for injection.

1Polysorbate 80 is used to water solubilize the oil-soluble vitamins A, D, E, and K.

Each 1 mL of Vial 2 contains:
Folic acid..... 140 mcg
Biotin..... 20 mcg
Vitamin B_{12} (cyanocobalamin)..... 1 mcg
Inactive ingredients: 75 mg mannitol, citric acid and/or sodium citrate for pH adjustment and water for injection.
Vitamin A 2,300 IU equals 0.7 mg
Vitamin D 400 IU equals 10 mcg
Vitamin E 7 IU equals 7 mg

Multiple vitamin preparation for intravenous infusion: INFUVITE Pediatric (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 80, permitting intravenous administration of these vitamins.
Contains no more than 30 mcg/L of aluminum (combined vials 1 and 2).

INDICATIONS AND USAGE

INFUVITE Pediatric is indicated as a daily multivitamin maintenance dosage for infants and children up to 11 years of age receiving parenteral nutrition.
INFUVITE Pediatric is also indicated in other situations where administration by the intravenous route is required. Such situations include surgery, extensive burns, fractures and other trauma, severe infectious diseases, and comatose 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 Pediatric (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. Blood vitamin concentrations should be periodically monitored to ensure maintenance of adequate levels, particularly in patients receiving parenteral multivitamins as their sole source of vitamins for long periods of time.

CONTRAINDICATIONS

INFUVITE Pediatric is contraindicated where there is a preexisting hypervitaminosis, 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

INFUVITE Pediatric is administered in intravenous solutions, which may contain 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.

PRECAUTIONS

Caution should be exercised when administering INFUVITE Pediatric to patients on warfarin sodium-type anticoagulant therapy. In such patients, vitamin K may antagonize the hypoprothrombinemic response to anticoagulant drugs. In such patients, periodic monitoring of prothrombin time/INR response is essential in determining the appropriate dosage of anticoagulant therapy.

Adequate blood levels of vitamin E are achieved when INFUVITE Pediatric is given to infants at the recommended dosage. Larger doses or supplementation with oral or parenteral vitamin E are not recommended because elevated blood levels of vitamin E may result.

Studies have shown that vitamin A may adhere to plastic, resulting in inadequate vitamin A administration in the doses recommended with INFUVITE Pediatric. Additional vitamin A supplementation may be required, especially in low-birth-weight infants.

Long-standing specific vitamin deficiencies may require additional therapeutic amounts of specific vitamins to supplement the maintenance vitamins provided by INFUVITE Pediatric.

In patients receiving parenteral multivitamins, blood vitamin concentrations should be periodically monitored to determine if vitamin deficiencies or excesses are developing.

Polysorbates have been associated with the E-Ferol syndrome (thrombocytopenia, renal dysfunction, hepatomagaly, cholestasis, ascites, hypotension and metabolic acidosis) in low-birth-weight infants. However, no such adverse reports have been associated with the use of pediatric multiple vitamins for infusion such as INFUVITE Pediatric.

INFUVITE Pediatric should be aseptically transferred to the infusion fluid.

Drug-Drug Interactions

Physical incompatibilities

INFUVITE Pediatric (Multiple Vitamins for Infusion) is not physically compatible with alkaline solutions or moderately alkaline drugs such as acetazolamide, and chlorothiazide sodium, aminopylline or sodium bicarbonate. INFUVITE Pediatric is not physically compatible with ampicillin and it may not be physically compatible with tetracycline HCl. It has also 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 physical compatibility of solutions and drugs with the vitamin infusion. In such circumstances, admixture or Y-site administration with vitamin solutions should be avoided.

Some of the vitamins in INFUVITE Pediatric may react with vitamin K bisulfite or sodium bisulfite; if bisulfite solutions are necessary, patients should be monitored for Vitamin A, thiamine, and ascorbic acid deficiencies.

Clinical Interactions

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 seizure frequency.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 requirements.

In patients with pernicious anemia, the hematological response to vitamin B12 therapy may be inhibited by concomitant administration of chloramphenicol.

Several vitamins have been reported to decrease the activity of certain antibiotics. Thiamine, riboflavin, pyridoxine, niacinamide, and ascorbic acid have been reported to decrease the antibiotic activity of erythromycin, kanamycin, streptomycin, doxycycline, and lincomycin. Bleomycin is inactivated in vitro by ascorbic acid and riboflavin.

Vitamin K may antagonize the hypoprothrombinemic effect of oral anticoagulants (see Precautions).

Consult appropriate references for additional specific vitamin-drug interactions.

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.

ADVERSE REACTIONS
There have been rare reports of anaphylactic reactions following parenteral multivitamin administration. Rare reports of anaphylactoid reactions have also been reported after large intravenous doses of thiamine. The risk, however, is negligible if thiamine is coadministered with other vitamins of the B group. There have been no reports of fatal anaphylactoid reactions associated with multivitamin preparations for infusion.
There have been rare reports of the following types of reactions:
Dermatologic – rash, erythema, pruritis
CNS – headache, dizziness, agitation, anxiety
Ophthalmic – diplopia
Allergic – urticaria, shortness of breath, wheezing and angioedema.

OVERDOSAGE
The possibility of hypervitaminosis A or D should be borne in mind. Clinical manifestations of hypervitaminosis A have been reported in patients with renal failure receiving
1.5 mg/day retinol. Therefore, vitamin A supplementation of renal failure patients should be undertaken with caution.

DOSAGE AND ADMINISTRATION
INFUVITE Pediatric is ready for immediate use in infants and children up to 11 years of age when added to intravenous infusion fluids.
INFUVITE Pediatric should not be given as a direct, undiluted intravenous injection as it may give rise to dizziness, faintness and possible tissue irritation.
A daily dose of INFUVITE Pediatric (4 mL of Vial 1 plus 1 mL of Vial 2) should be added directly to not less than 100 mL of intravenous dextrose, saline or similar infusion solutions.
For administration to infants weighing < 1 kg:
The daily dose is 30% of the contents of Vial 1
(1.2 mL) and of Vial 2 (0.3 mL). Do not exceed this daily dose. Supplemental vitamin A may be required for low-birth-weight infants.
For administration to infants weighing ≥1 kg and < 3 kg: The daily dose is 65% of the contents of Vial 1 (2.6 mL) and of Vial 2 (0.65 mL). Do not exceed this daily dose. Supplemental vitamin A may be required for low-birth-weight infants.
For administration to infants and children weighing ≥3 kg up to 11 years of age: The daily dose is the entire contents of Vial 1 (4 mL) and of Vial 2 (1 mL), unless there is clinical or laboratory evidence for increasing or decreasing the dosage.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
After INFUVITE Pediatric is diluted in an intravenous infusion, the resulting solution is ready for immediate use. Some of the vitamins in this product, particularly A, D, and riboflavin, are light sensitive, therefore, exposure to light should be minimized.
DISCARD ANY UNUSED PORTION

HOW SUPPLIED
INFUVITE Pediatric – NDC 54643-5646-0, is available in boxes containing 2 vials – Vial 1 (4 mL) and Vial 2 (1 mL), both vials to be used for a single dose.
INFUVITE Pediatric – NDC 54643-5646-1, is available in boxes containing 10 vials – 5 each of Vial 1 (4 mL) and 5 each of Vial 2 (1 mL), one Vial 1 plus one Vial 2 to be used for a single dose.

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

Rx only
Manufactured by
Sandoz Canada Inc.
145 Jules-Leger Street Boucherville, QC, Canada J4B 7K8
Distributed by
Baxter Healthcare Corporation
Clintec Nutrition Division Deerfield, IL 60015 USA
Printed in Canada
D1006129 Rev. September 2007
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