

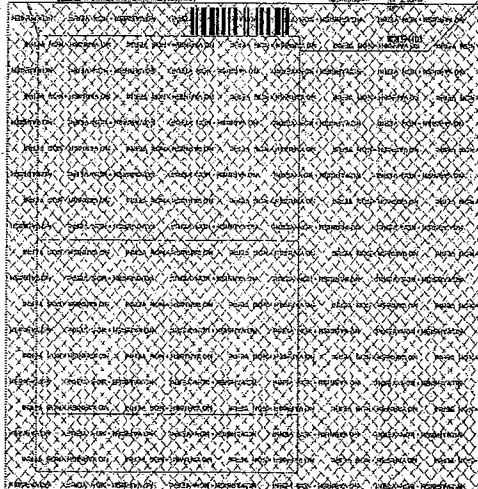
**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-646

APPROVED LABELING

X = 15+23/32 Y = 8+19/64
 wgn394463
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 PRINTED SIDE



249061 NDC 54643 5647 0

BEAVER

INFUITEPEDiatric
 PHARMACY BULK PACKAGE

Multiple Vitamins for Infusion

**PHARMACY BULK PACKAGE
 NOT FOR DIRECT INFUSION**



For intravenous infusion after
 dilution only.
STERILE
 Rx only
 Contents: Vial 1 (40 mL fill in 50 mL)
 and Vial 2 (10 mL),
 Both vials combined produce
 10 single doses.
 Store under refrigeration, 2-8 °C
 (36-46 °F)

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.

DISCARD UNUSED PORTION.

USUAL DOSAGE: See Package
 Insert.

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 PHARMACY BULK PACKAGE

Multiple Vitamins for Infusion

Each 4 mL of Vial 1 contains:

Vitamin C	80 mg
Vitamin B ₁	200 IU
Vitamin B ₂	200 IU
Vitamin B ₆	2.2 mg
Thiamine (B ₁)	1.4 mg
Riboflavin (B ₂)	1.4 mg
Pantoic acid (B ₃)	2 mg
Pyridoxine HCl (B ₆)	2 mg
Unsaturated	2 mg
Vitamin E (d-α-tocopherol acetate)	20 IU
Vitamin K ₁ (phytylphosphate)	20 IU
Vitamin K ₂ (menaquinone 10, sodium hydroxide and/or hydrochloride salt for pH adjustment and water for injection)	20 IU

Each 1 mL of Vial 2 contains:

Stimulin	100 mcg
Stimulin	20 mcg
Cyanocobalamin (B ₁₂)	1 mcg

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



Distributed by:
 Baxter Healthcare Corporation
 Chinese Medicine Division
 Deerfield, IL 60015 USA

Manufactured by:
 SAE Pharma Inc.
 50, Canada JRB 783

Made in Canada
INFUITE is a trademark of
 SAE Pharma Inc.

100372

SAB-Pharma USA

Product Code 56470_1002474
Dieline



Le 15 / 01 / 2004

COPIE FINALE APPROUVÉE

- Modification d'étiquette
- Nouveau produit SABEX
- Nouveau produit SAB-Pharma USA

2A9061

40 mL in a 50 mL Vial

INFINITY PED
Multiple Vitamins for Infusion

VIAL 1

For intravenous infusion after dilution only.
STERILE
Store under refrigeration, 2-8 °C (36-46 °F).
Protect from light.

Each 5 mL of Vial 1 contains:

Vitamin C	40 mg
Vitamin A	300 IU
Vitamin D	400 IU
Thiamine (B1)	1.7 mg
Riboflavin (B2)	1.4 mg
Pyridoxine HCl (B6)	1 mg
Nicotinamide	17 mg
Coenzyme Q10	10 mg
Vitamin E (d-α-tocopheryl acetate)	6.7 IU
Vitamin K	0.2 mg

Trace the contents of Vial 2 into Vial 1 in people on 5 mL single doses. Each 5 mL single dose should be added to not less than 100 mL of infusion fluid.

* Contains no more than 200 mcg/L of aluminum (combined with 1 and 2).

Once dipropyl system has been compromised, do not use. Contents should be discarded within 4 hours of first use.

USUAL DOSAGE: See Package Insert.

Roctac
Distributed by: Baxor Healthcare Corporation
Chicago, IL 60631, USA
Desfield, IL, Baxor USA 102574

PHARMACY BULK PACKAGE
NOT FOR DIRECT INFUSION

Baxter

**INFUVITE
PEDIATRIC**

**PHARMACY
BULK PACKAGE**

**Multiple Vitamins
for Infusion**

Rx only

**For intravenous infusion
after dilution only.**



0 57513192471 2

Pyridoxine HCl (Vitamin B₆) 1 mg
 Niacinamide 17 mg
 Dexpanthenol
 (as D-panthothenyl alcohol) 5 mg

Vitamin E* (dl- α -tocopheryl acetate) 7 IU
 Vitamin K₁* 0.2 mg

Inactive ingredients: 50 mg 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 vitamins A, D, E and K.

Each 1 mL of Vial 1 contains:

Folic acid 140 mcg
 Biotin 20 mcg
 Vitamin B₁₂ (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

**Pharmacy
Bulk Package
Not for Direct
Infusion**

DESCRIPTION

INFUVITE PEDIATRIC (PHARMACY BULK PACKAGE) is a sterile product consisting of two vials: 1 each of Vial 1 (40 mL fill in 50 mL) and Vial 2 (10 mL), 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 4 mL of Vial 1 contains:

Ascorbic acid (Vitamin C) 80 mg
 Vitamin A* (as palmitate) 2 300 IU
 Vitamin D₃* (cholecalciferol) 400 IU
 Thiamine (Vitamin B₁)
 (as the hydrochloride) 1.2 mg
 Riboflavin (Vitamin B₂)
 (as riboflavin 5-phosphate
 sodium) 1.4 mg

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 wait the development of clinical signs of vitamin deficiency before initiating vitamin therapy.

INFUVITE PEDIATRIC (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.

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

Allergic reaction has 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.

PRECAUTIONS

Caution should be exercised when administering **INFUVITE PEDIATRIC (PHARMACY BULK PACKAGE)** 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**

(**PHARMACY BULK PACKAGE**) is given to infants at the recommended dosage. Larger doses of 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 (PHARMACY BULK PACKAGE)**. 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 (PHARMACY BULK PACKAGE)**.

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, hepatomegaly, cholestasis, ascites, hypopneumonia 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 (PHARMACY BULK PACKAGE)**.

INFUVITE PEDIATRIC (PHARMACY BULK PACKAGE) should be aseptically transferred to the infusion fluid.

DRUG-DRUG INTERACTIONS

Physical Incompatibilities: INFUVITE PEDIATRIC (PHARMACY BULK PACKAGE) (Multiple Vitamins for Infusion) is not physically compatible with alkaline solutions or moderately alkaline drugs such as acetazolamide, and chlorothalidate sodium, amniopline or sodium bicarbonate. **INFUVITE PEDIATRIC (PHARMACY BULK PACKAGE)** 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 (PHARMACY BULK PACKAGE)** 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. Concurrent 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 chlorzampfenicol.

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 tetracycline. Biocytin 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, mutagenesis and fertility studies have not been performed.

WARNINGS

INFUVITE PEDIATRIC (PHARMACY BULK PACKAGE) is administered in intravenous solutions, which may contain aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parental 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.

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 co-administered 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.

DOSE AND ADMINISTRATION

INFUVITE PEDIATRIC (PHARMACY BULK PACKAGE) is ready for immediate use in infants and children up to 11 years of age when added to intravenous infusion fluids.

INFUVITE PEDIATRIC (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 PEDIATRIC (PHARMACY BULK PACKAGE) for intravenous feeding should be done by transferring the contents of Vial 2 into the contents of Vial 1 to provide ten 5 mL single doses. One daily dose of INFUVITE PEDIATRIC (PHARMACY BULK PACKAGE) should be added directly to not less than 100 mL of intravenous dextrose, saline or similar solutions. Discard any unused portion.

Daily doses in pediatric patients are determined as follows:

For administration to infants weighing < 1 kg: The daily dose is 30% of the contents of a 5 mL single dose (1.5 mL of combined vials 1 and 2). 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 a 5 mL single dose (3.25 mL of combined vials 1 and 2). 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 an entire 5 mL single dose of combined vials 1 and 2, 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 (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, 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 PEDIATRIC (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 PEDIATRIC (PHARMACY BULK PACKAGE) – NDC 54643-56470, is available in boxes containing 2 vials – 1 each of Vial 1 (40 mL fill in 50 mL Vial) and Vial 2 (10 mL). Mix contents of Vial 2 with Vial 1 to provide 10 single 5 mL doses.

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

Distributed by:
Baxter Healthcare Corporation
Clinec Nutrition Division
Deerfield, IL 60015 USA

Manufactured by:
SAB-PHARMA INC.
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