**Contraindications**

INFUVITE ADULT is contraindicated where there is a preexisting hypersensitivity to any of the vitamins or excipients in the product.

Anaphylactic 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 megablastic anemia, as the folic acid and the cyanocobalamin in the vitamin solution can mask serum deficiencies.

**Warnings**

This product contains aluminum that may be toxic. Aluminum may reach the serum levels of blood concentration of aluminum, and those in infants, infants, and young children. Premature newborns and young children should be examined when administering INFUVITE ADULT to patients with a metabolic or nutritional state that may be associated with aluminum. Premature newborns and young children may react with aluminum, as they have a high demand for aluminum.

**Precautions**

If this formulation is the source of vitamins for long periods of time, blood concentration of aluminum, and those of the products, such as aluminum, may be increased. Aluminum, and any other metal, may cause false negative results in the laboratory tests for vitamin deficiencies.

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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 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
Ophthalmic – diplopia
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 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.

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 is ready for immediate use in adults and children aged 11 years and older when added to intravenous infusion fluids.

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

How Supplied

INFUVITE ADULT – NDC 5464-3-5649-1, is available in boxes containing 10 vials - 5 each of Vial 1 (5 mL) and Vial 2 (5 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

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**INFUVITE® ADULT PHARMACY BULK PACKAGE**

**Multiple Vitamins for Infusion**

**Rx Only**

For intravenous infusion after dilution only.

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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
- Thiamine (Vitamin B1) ............................................... 6 mg
- Riboflavin (Vitamin B2) ............................................. 3 mg
- Pyridoxine HCl (Vitamin B6) ............................... 6 mg
- Niacinamide .................................................. 40 mg
- Desferrioxamine .................................................. 10 mg
- Folic acid ...................................................... 60 mcg
- Cyanocobalamin .................................................. 5 mcg
- DL-α-tocopheryl acetate ......................................... 10 IU

Active ingredients: 3.4% polyethylene glycol 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
- Betaine .......................................................... 60 mg
- Vitamin B12 (cyanocobalamin) ......................... 5 mcg
- Polysorbate 80 is used to water solubilize the oil-soluble vitamins A, D, E, K, and K.

**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, severe infectious disease, and cirrhotic 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.

**Contraindications**

**INFUVITE ADULT (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.

**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 levels of aluminum at greater than 4 to 5 mg/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, C, D, 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 vitamins provided in **INFUVITE ADULT (PHARMACY BULK PACKAGE)**.

**Drug – Drug/Solution Interactions**:

- Caution 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 anacardic acid, chlorothiazide, sodium amphotere, 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 physical compatibility of solutions and drugs with the vitamin infusion. In such circumstances, admixture or Y-site administration of vitamin solutions should be avoided.

**Contraindications**

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**Precautions**

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 seizures activity. Conversely, phenytoin may decrease 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 hematologic 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, dicloxacillin, and lincomycin. Bleomycin 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 activity of Vitamin A and/or 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 requirement 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
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Overdosage
The fat-soluble vitamins A, D, and E can accumulate to harmful levels. The possibility of hypercalcemia A or D should be borne in mind. Clinical manifestations of hypercalcemia A have been reported in patients with renal failure receiving 3.5 mg/day retinol. Therefore, vitamin A supplementation of renal failure patients should be undertaken with caution. 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 dextrose, saline or similar infusion 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, 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 54643-5650-2, 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 to 8°C (36-46°F).

Manufactured by Sandoz Canada Inc. 145 Jules-Léger Street Boucherville, Québec, Canada, J4B 7K8

Distributed by Baxter Healthcare Corporation Center Valley Division Deerfield, IL 60015 USA

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INSTRUCTIONS

PRODUCTION ART/INFOPHONIE

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(verso/back): ............................................................ PMS 287
dimensions (mm): à plat/flat: ........................................ 136 X 296
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Les fichiers de production de Sandoz Canada ne sont pas conçus avec le chevauchement des couleurs.
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