Physicians' Prescribing Information

MULTI-12/K_1 PEDIATRIC

Multiple Vitamins for Infusion

Multi-12/K_1 Pediatric is a multiple vitamin supplement containing the following vitamins:

Vial 1	Ascorbic acid	80 mg
	Vitamin A	2300 IU
	Vitamin D	400 IU
	Thiamine (as hydrochloride)	1.2 mg
	Riboflavin (as phosphate)	1.4 mg
	Pyridoxine hydrochloride	1 mg
	Niacinamide	17 mg
	d-Panthenol	5 mg
	Vitamin E (*dl*-alpha tocopheryl acetate)	7 IU
	Vitamin K_1	0.2 mg
	Also contains: polysorbate 80, 1.25%, sodium hydroxide and/or hydrochloric acid to adjust pH and water for injection.	
Vial 2	Biotin	20 mcg
	Folic Acid	140 mcg
	Vitamin B_{12} (cyanocobalamin)	1 mcg
	Also contains: mannitol 7.5 %, sodium citrate and/or citric acid to adjust pH and water for injection.	

INDICATIONS

Multi-12/K_1 Pediatric is indicated for use as a multiple vitamin supplement for infants and children up to 11 years of age.

Its administration helps to maintain plasma vitamin levels and helps to prevent depletion of endogenous stores of the vitamins and development of subsequent deficiency symptoms.

It is also indicated in other situations where there are increased requirements for vitamins due to stress situations such as surgery, extensive burns, fractures and other trauma, severe infectious diseases, and comatose states.

The physician should not await the development of clinical signs of vitamin deficiency before initiating vitamin therapy. The use of a multivitamin product obviates the need to speculate on the status of individual vitamin nutriture.

Multi-12/K_1 Pediatric, through the intake of these necessary vitamins, contributes towards the maintenance of the body's normal resistance and repair processes.

CONTRAINDICATIONS

Known hypersensitivity to any of the vitamins in this product or a pre-existing hypervitaminosis.

PRECAUTIONS

General: Unlike the adult formulation, Multi-12, and the original pediatric formulation, Multi-12 Pediatric, this product contains Vitamin K_1.

Caution should be used when administering **Multi-12/K_1 Pediatric** to neonates undergoing concomitant parenteral therapy with drugs containing polysorbate 80. If deemed necessary, to limit the concomitant administration of polysorbate 80, discontinue **Multi-12/K_1 Pediatric** therapy for a few days and resume it when the other drug therapy has been ceased.

Drug Interactions: **Multi-12/K_1 Pediatric** is not physically compatible with acetazolamide, aminophylline, ampicillin, or moderately alkaline solutions. It has been reported that folic acid is unstable in the presence of calcium salts such as calcium gluconate.

Carcinogenicity: Carcinogenicity studies have not been performed.

ADVERSE REACTIONS

There have been rare reports of anaphylactoid reactions following large intravenous doses of thiamine. The risk, however, is negligible if thiamine is co-administered with other B vitamins. There have been no reports of fatal anaphylactoid reactions associated with pediatric multivitamin preparations.

There have been rare reports of the following types of reactions:
Dermatologic: rash, erythema, pruritus.
CNS: headache, dizziness, agitation, anxiety.
Ophthalmic: diplopia.
Allergic: urticaria, periorbital and digital edema.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

SYMPTOMS AND TREATMENT OF OVERDOSAGE

The fat-soluble vitamins A, D and E can accumulate to harmful levels. Water-soluble vitamins, however, are readily excreted in the urine. Treatment of vitamin overdosage usually consists of withdrawal of the vitamin.

DOSAGE AND ADMINISTRATION

Multi-12/K_1 Pediatric should not be given as a direct, undiluted intravenous injection as it may give rise to dizziness, faintness and possible tissue irritation. **Multi-12/K_1 Pediatric must be diluted prior to intravenous infusion.**

For administration to infants and children weighing ≥ 3 kg up to 11 years of age: Add one daily dose [the entire contents of Vial 1 (4 mL) and of Vial 2 (1 mL)] to not less than 100 mL of 5% Dextrose Injection or 0.9% Sodium Chloride Injection.

For administration to infants weighing ≥ 1500 g and < 3 kg: The daily dose is 65% of the contents of Vial 1 and Vial 2, added to not less than 100 mL of 5% Dextrose Injection or 0.9% Sodium Chloride Injection.

For administration to infants weighing < 1500 g: The daily dose is 30% of the contents of Vial 1 and Vial 2, added to not less than 100 mL of 5% Dextrose Injection or 0.9% Sodium Chloride Injection.

After **Multi-12/K_1 Pediatric** is diluted in an intravenous infusion, the resulting solution should be refrigerated unless it is to be administered immediately, and in any event should be administered within 24 hours. Discard any unused portions.

Some of the vitamins in this product, particularly vitamins A, D, and riboflavin, are light-sensitive. Exposure to light should be minimized.

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

AVAILABILITY OF DOSAGE FORMS

Multi-12/K_1 Pediatric is available as five single use two vial set: 5 x Vial 1 containing 4 mL and 5 x Vial 2 containing 1 mL.

Store between 2 and 8 °C.
Protect from light.
Discard unused portion.

Latex-Free Stoppers: Stoppers contain no dry natural rubber.

Drug Registration No.: 139.34.30692.00

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IMPORTER
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