LIVITA CHILDREN- folate, multivitamin liquid PureTek Corporation

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Livita Children

Liquid Multivitamin

DESCRIPTION:

Serving Size: 15 mL

Servings per container: 47

Vitamin A (as Retinyl Acetate)	300 mcg RAE
Vitamin C (as Ascorbic Acid)	66.67 mg
Vitamin D3 (as Cholecalciferol)	3.33 mcg
Vitamin E (as D-Alpha Tocopheryl Acetate)	10 mg
Thiamin (as Thiamine Mononitrate)	0.4 mg
Riboflavin	0.43 mg
Niacin (as Niacinamide)	2.67 mg
Vitamin B6 (as Pyridoxine Hydrochloride)	0.57 mg
Folate (as L-5-Methyltetrahydrofolate calcium	salt)566 mcg DFE
(333 mcg of L-5-Methylfolate)	
Vitamin B12 (as Methylcobalamin)	0.8 mcg
Biotin (as D-Biotin)	10 mcg
Pantothenic Acid (as D-Calcium Pantothenate	e) 1.67 mg
Choline (as Choline Bitartrate)	
Calcium (as Calcium Citrate)	
Magnesium (as Magnesium Citrate)	
Zinc (as Zinc Picolinate)	0.67 mg
Inulin (as Helianthus Tuberosus Root Extract) 166.67 mg

Other Ingredients: Aqua (Water), Organic Agave Syrup, Carrageenan, Citrus Extract, Flavor, Glycerin, Potassium Sorbate, Organic Stevia Rebaudiana Leaf Extract.

INDICATIONS AND USAGE:

Livita™ liquid is indicated to provide significant amounts of essential vitamins and minerals, including Vitamins A, C, D, E, thiamine, riboflavin, niacin, vitamin B6, vitamin B12, folate, calcium, magnesium, and zinc, to supplement the diet. This comprehensive nutrient profile helps prevent nutritional deficiencies of these vitamins and minerals, ensuring that the specific dietary needs of adults and children are met to support overall health, energy, and vitality. The product is specially formulated to target common vitamin and mineral gaps in adults, thus promoting optimal health, immune function, bone strength, and metabolic balance. It is intended to be used under the guidance of a licensed healthcare practitioner to ensure that any potential for nutritional deficiency is

addressed in a manner that supports the individual's overall health and wellbeing.

Contraindications:

This product is contraindicated in patients with known hypersensitivity to any of its ingredients.

WARNING:

In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Precaution Section

Folate doses above 0.1 mg daily may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations remain progressive. There is a potential danger in administering folate to patients with undiagnosed anemia since folate may obscure the diagnosis of pernicious anemia by alleviating the hematologic manifestations of the disease while allowing the neurologic complications to progress. This may result in severe nervous system damage before the correct diagnosis is made. Adequate doses of vitamin B12 may prevent, halt, or improve the neurologic changes caused by pernicious anemia.

The patient's medical conditions and consumption of other drugs, herbs, and/or supplements should be considered.

For use on the order of a licensed healthcare practitioner. Call your doctor about side effects. To report side effects, call PureTek Corporation at 1-877-921-7873 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Adverse Reactions:

Folate: Allergic sensitizations have been reported following both oral and parenteral administration of folate. Adverse reactions have been reported with specific vitamins and minerals but generally at levels substantially higher than those contained herein. However, allergic, and idiosyncratic reactions are possible at lower levels.

Dosage and Administration:

Livita™ Liquid Multivitamin for Children: The usual child dose is 1-2 teaspoons or 5-10 mL daily.

Or as prescribed by a licensed healthcare practitioner.

How Supplied:

Livita™ Liquid Multivitamin for Children is available in an 8 fl.oz. bottle with an NDC of 59088-660-16.

All prescription substitutions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product.

STORAGE:

Do not use if bottle seal is broken. KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

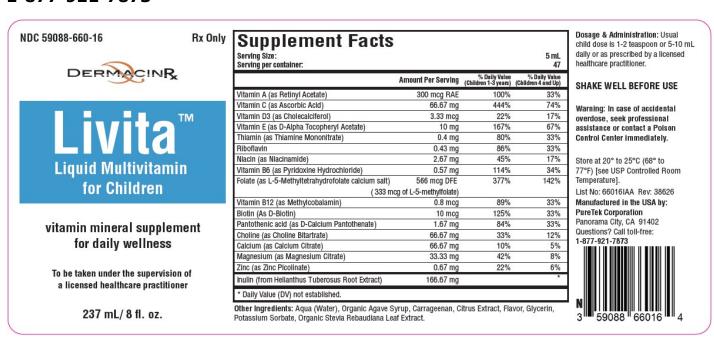
Store at controlled room temperature 20° to 25°C (68° to 77°F). [See USP]. Protect from light and moisture and avoid excessive heat.

Livita™

Manufactured in the USA by:

PureTek Corporation Panorama City, CA 91402 Ouestions? Call toll-free:

1-877-921-7873



LIVITA CHILDREN

folate, multivitamin liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:59088-660
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CHOLINE BITARTRATE (UNII: 6K2W7T9V6Y) (CHOLINE - UNII:N91BDP6H0X)	CHOLINE	66.67 mg in 1 mL
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	3.33 ug in 1 mL
VITAMINI A ACETATE (LINIII, 21 E2DODGOV) (VITAMINI A LINIII, 01 C 40110DOT)	VITABAINI A	300 ug

VII AMIN A ACETATE (UNII: SESSUSUOUT) (VII AMIN A - UNII:0104000001)	VII AMIIN A	in 1 mL
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	AS CORBIC ACID	66.67 mg in 1 mL
.ALPHATOCOPHEROL ACETATE, D- (UNII: A7E6112E4N) (.ALPHATOCOPHEROL, D UNII:N9PR3490H9)	.ALPHA TOCOPHEROL, D-	10 mg in 1 mL
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	0.4 mg in 1 mL
RIBOFLAVIN (UNII: TLM29760FR) (RIBOFLAVIN - UNII:TLM29760FR)	RIBOFLAVIN	0.43 mg in 1 mL
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	2.67 mg in 1 mL
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII: KV2JZ 1BI6Z)	PYRIDOXINE	0.57 mg in 1 mL
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLATE CALCIUM	333 ug in 1 mL
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	0.8 ug in 1 mL
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	10 ug in 1 mL
ZINC PICOLINATE (UNII: ALO92031SE) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.67 mg in 1 mL
MAGNESIUM CITRATE (UNII: RHO2601T9V) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CITRATE	33.33 mg in 1 mL
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	1.67 mg in 1 mL
CALCIUM CITRATE (UNII: MLM29U2X85) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CITRATE	66.67 mg in 1 mL
INULIN (UNII: JOS53KRJ01) (INULIN - UNII:JOS53KRJ01)	INULIN	166.67 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
AGAVE TEQUILANA JUICE (UNII: GVG8G02070)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
CARRAGEENAN (UNII: 5C69YCD2YJ)		
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)		
CITRUS FRUIT (UNII: XDK00Z8012)		

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-660- 16	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/18/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/18/2023	
other			

Labeler - PureTek Corporation (785961046)

Revised: 12/2023 PureTek Corporation