POLY-VI-FLOR- multivitamin and fluoride supplement suspension/ drops Aytu Therapeutics LLC

Poly-Vi-Flor 0.25 mg Arcofolin Drops with Iron

Poly-Vi-Flor

(Multivitamin and Fluoride Supplement)

Health Claim

Multivitamin and Fluoride Supplement

Supplement Facts Serving Size 1 mL • Servings Per Cor	ntainer 50			
		% Daily Value		
Amount Per 1 mL		Infants through 12 months	Children 1 through 3 years of age	
vitamin D (as cholecalciferol)	10 mcg	100%	67%	
vitamin E (as d-alpha-tocopheryl acetate)	3.35 mg	67%	56%	
niacin (as niacinamide)	8 mg	200%	133%	
vitamin B ₆ (as pyridoxine HCl)	0.4 mg	133%	80%	
folate (as Arcofolin)	200 mcg DFE	250%	133%	
iron (as ferrous sulfate)	7 mg	64%	100%	
fluoride (as sodium fluoride)	0.25 mg	*	*	

^{*}Daily Value not established

Ingredients: Glycerin, Water, Fructose, Ascorbic Acid, Polysorbate 80, Natural Flavoring, Soy Lecithin, Potassium Sorbate

Poly-Vi-Flor drops are specially designed to help meet the nutritional needs of your growing infant or toddler.

- **Poly-Vi-Flor** Drops are the ideal vitamin supplement during your child's transition to solid foods, during growth spurts, or for the picky eater.
- One daily dose of Poly-Vi-Flor Drops provides 5 essential vitamins and is fruit flavored.
- Drops are dye-free and gluten-free.

Dosage and Administration

How to Use the Enclosed Dropper

Fill the dropper to the 1 mL line to provide the full daily dosage. Use full dosage, regardless of age or weight, unless your child's doctor recommends a different dosage.

Dispense with a single squeeze of the dropper bulb. It is normal for a small amount to remain in the tip.

Dosing Tips

Drops may be given by dispensing directly into the mouth. Drops may also be mixed with formula, fruit juice, cereal or other foods to increase your child's acceptance.

Shake well before use.

This product comes with a child-resistant cap. Refrigeration not required. After opening, store away from direct sunlight.

Warning

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Arcofolin® is a registered trademark of Merck KGaA, Darmstadt, Germany

Distributed by: Aytu Therapeutics, LLC Denver, CO 80237 1-855-298-8246 www.aytubio.com

Principal Display Panel

PRINCIPAL DISPLAY PANEL - Poly-Vi-Flor 0.25 mg Acrofolin Drops with Iron

23594-605-50

Poly-Vi-Flor®

Essential Vitamins for Infants & Toddlers

FRUITY FLAVOR

MULTIVITAMIN AND FLUORIDE SUPPLEMENT DROPS

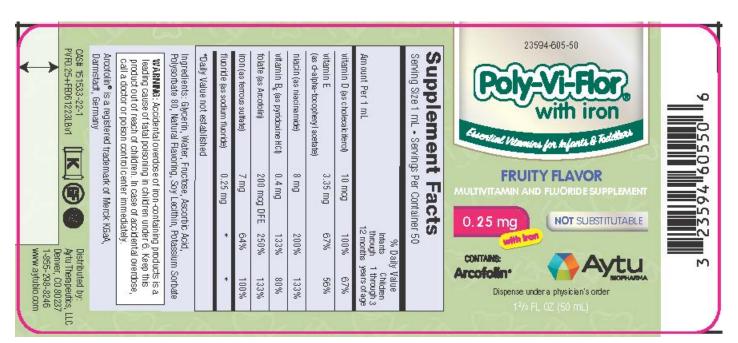
0.25 mg with Iron

NOT SUBSTITUTABLE

CONTAINS: Arcofolin

1 2/3 FL OZ (50 mL)

Aytu Therapeutics, LLC





multivitamin and fluoride supplement suspension/ drops

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:23594-605
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug in 1 mL	
.ALPHATOCOPHEROL ACETATE, D- (UNII: A7E6112E4N) (.ALPHATOCOPHEROL, D UNII:N9PR3490H9)	.ALPHA TOCOPHEROL, D-	3.35 mg in 1 mL	
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	8 mg in 1 mL	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	0.4 mg in 1 mL	
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	200 ug in 1 mL	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.25 mg in 1 mL	
FERROUS SULFATE (UNII: 39R4TAN1VT) (FERROUS CATION - UNII:GW895810WR)	FERROUS CATION	7 mg in 1 mL	

Inactive Ingredients			
Strength			
ASCORBIC ACID (UNII: PQ6CK8PD0R)			
POLYSORBATE 80 (UNII: 60ZP39ZG8H)			
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:23594-605-50	1 in 1 PACKAGE		
1		50 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		09/15/2023	

Labeler - Aytu Therapeutics LLC (117244733)

Revised: 9/2023 Aytu Therapeutics LLC