

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

## **Poly-Vi-Flor 0.25 mg Arcofolin Drops**

### **Poly-Vi-Flor**

(Multivitamin and Fluoride Supplement with 0.25 mg of Fluoride)

### **Health Claim**

Multivitamin and Fluoride Supplement

<b>Supplement Facts</b>			
<b>Serving Size 1 mL • Servings Per Container 50</b>			
Amount Per 1 mL		<b>% Daily Value</b>	
		<b>Infants through 12 months</b>	<b>Children 1 through 3 years of age</b>
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 <sub>6</sub> (as pyridoxine HCl)	0.4 mg	133%	80%
folate (as Arcofolin)	200 mcg DFE	250%	133%
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 7 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**

As with all medicines, keep out of the reach of children.

**U.S. Patent Numbers:** 5,997,915; 6,254,904; 6,011,040; 6,441,168

Arcofolin<sup>®</sup> is a registered trademark of Merck KGaA, Darmstadt, Germany

**Distributed by:** Aytu Therapeutics, LLC  
Englewood, CO 80112  
1-855-298-8246  
www.aytubio.com

### **Principal Display Panel**

**PRINCIPAL DISPLAY PANEL - Poly-Vi-Flor with 0.25 mg of Fluoride**

23594-805-50

Poly-Vi-Flor<sup>®</sup>

Essential Vitamins for Infants & Toddlers

**FRUITY FLAVOR**

**MULTIVITAMIN AND FLUORIDE SUPPLEMENT DROPS**

**0.25 mg**

**NOT SUBSTITUTABLE**

CONTAINS:Arcofolin

1 2/3 FL OZ (50 mL)

Aytu Therapeutics, LLC

0 055081 96552 3



23594-805-50

**FRUITY FLAVOR**

MULTIVITAMIN AND FLUORIDE SUPPLEMENT  
DROPS

**0.25 mg**

NOT SUBSTITUTABLE

CONTAINS:

**Arcofolin<sup>®</sup>**



1 1/2 FL OZ (50 mL)

Dispense under a physician's order

**Supplement Facts**

Serving Size 1 mL • Servings Per Container 50

Amount Per 1 mL	% Daily Value	
	Infants through 12 months	Children 1 through 3 years of age
Vitamin D (as cholecalciferol)	10 mcg	100%
Vitamin E (as d-alpha-tocopheryl acetate)	3.35 mg	67%
Niacin (as niacinamide)	8 mg	200%
Vitamin B <sub>6</sub> (as pyridoxine HCl)	0.4 mg	133%
Folate (as Arcobin)	200 mcg DFE	250%
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  
Arcofolin<sup>®</sup> is a registered trademark of Merck KGaA, Darmstadt, Germany

CAS# 151503-22-1  
PVE 25MLU41123LbV1



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## POLY-VI-FLOR

multivitamin and fluoride supplement suspension/ drops

### Product Information

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRC:23594-805
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug in 1 mL
<b>.ALPHA.-TOCOPHEROL ACETATE, D-</b> (UNII: A7E6112E4N) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL, D-	3.35 mg in 1 mL

<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	8 mg in 1 mL
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	0.4 mg in 1 mL
<b>LEVOMEFOLATE CALCIUM</b> (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	200 ug in 1 mL
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.25 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>FRUCTOSE</b> (UNII: 6YSS42VSEV)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:23594-805-50	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		08/11/2023	

**Labeler** - Aytu Therapeutics LLC (117244733)

Revised: 8/2023

Aytu Therapeutics LLC