

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

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**Poly-Vi-Flor 0-25 mg Drops**

## **Poly-Vi-Flor**

(Multivitamin with 0.25 mg of Fluoride)

**Poly-Vi-Flor** Drop are specifically 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.

## **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 (from Metafolin®)	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

## **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.

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

**Distributed by:** Aytu Therapeutics, LLC  
Denver, CO80237  
1-855-298-8246  
www.aytubio.com

## **Principal Display Panel**

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

23594-550-50

Poly-Vi-Flor<sup>®</sup>

Essential Vitamins for Infants & Toddlers

**FRUITY FLAVOR**

**MULTIVITAMIN AND FLUORIDE SUPPLEMENT**

**0.25 mg**

**NOT SUBSTITUTABLE**

CONTAINS: METAFOLIN

1 2/3 FL OZ (50 mL)

Aytu BioPharma

Dispense under a physician's order

**Bottle Label**

9  
 3 23594 55050

23594-550-50

**Poly-Vi-Flor**  
*Essential Vitamins for Infants & Toddlers*

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 MULTIVITAMIN AND FLUORIDE SUPPLEMENT

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

CAS# 151533-22-1  
 PNF: 25ML061417LB09



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 1-855-298-8346  
 www.aytubio.com

**Carton Label**



**Supplement Facts**  
Serving Size 1 mL • Servings Per Container 50

Amount Per 1 mL	% Daily Value	
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Folate (from Metafolin®) 200 mcg DFE	250%	133%
Fluoride (as sodium fluoride) 0.25 mg	*	*

\*Daily Value not established.

Ingredients: Glycerin, Water, Fructose, Ascorbic Acid, Polyethylene Glycol, Natural Flavoring, Soy Lecithin, Potassium Sorbate

Metafolin® is a registered trademark of Merck KGaA, Darmstadt, Germany  
CAS# 191533-22-1

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Aytu Therapeutics, LLC  
Denver, CO 80237  
1-855-268-8246  
www.aytubio.com

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QUESTIONS OR COMMENTS?  
Please call Aytu BioPharma at 1-855-298-8246

PVF-25ML061417C1V8

**0.25 mg** NOT SUBSTITUTABLE

CONTAINS METAFOLIN®

DYE FREE GLUTEN FREE 1 2/3 FL OZ (50 mL)



**POLY-VI-FLOR**

multivitamin and fluoride supplement suspension/ drops

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:23594-550
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	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL, D-	3.35 mg in 1 mL	
NIACINAMIDE (UNII: 2EY5109DA) (NIACINAMIDE - UNII:2EY5109DA)	NIACINAMIDE	8 mg	

<b>NIACINAMIDE</b> (UNII: 23A316RD4) (NIACINAMIDE - UNII:23A316RD4)	NIACINAMIDE	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:23594-550-50	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		12/23/2022	

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

Revised: 3/2023

Aytu Therapeutics LLC