

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

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**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<br/>through<br/>12 months</b> | <b>Children<br/>1 through 3<br/>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®**



1 2/3 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                   | *                                 |

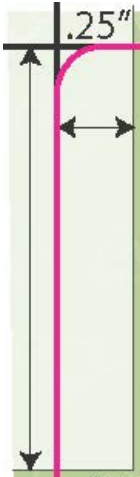
\*Daily Value not established

Ingredients: Glycerin, Water, Fructose, Ascorbic Acid, Polysorbate 80, Natural Flavoring, Soy Lecithin, Potassium Sorbate  
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PVE 25MLU41123LbV1



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| <b>POLY-VI-FLOR</b>   |                    |                           |                 |
|---|--------------------|---------------------------|-----------------|
| multivitamin and fluoride supplement suspension/ drops  |                    |                           |                 |
| <b>Product Information</b>  |                    |                           |                 |
| <b>Product Type</b>   | DIETARY SUPPLEMENT | <b>Item Code (Source)</b> | NHRIC:23594-805 |
| <b>Route of Administration</b>  | ORAL               |                           |                 |
| <b>Active Ingredient/Active Moiety</b>  |                    |                           |                 |
| <b>Ingredient Name</b>  |                    | <b>Basis of Strength</b>  | <b>Strength</b> |
| <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<br>in 1 mL    |
| <b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)   | PYRIDOXINE       | 0.4 mg<br>in 1 mL  |
| <b>LEVOMEFOLATE CALCIUM</b> (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC) | LEVOMEFOLIC ACID | 200 ug<br>in 1 mL  |
| <b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)          | FLUORIDE ION     | 0.25 mg<br>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