

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 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%	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

23594-605-50

Poly-Vi-Flor
with iron

Essential Vitamins for Infants & Toddlers

FRUITY FLAVOR

MULTIVITAMIN AND FLUORIDE SUPPLEMENT

0.25 mg

with iron

NOT SUBSTITUTABLE

CONTAINS:
Arcofolin

Aytu
BIOPHARMA

Dispense under a physician's order

1 2/3 FL OZ (50 mL)



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%	67%
vitamin E	3.35 mg	67%	95%
(as d-alpha-tocopheryl acetate)			
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

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

QAS# 151533-22-1
PVFD 25+FE061223C1.B.V1



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

Poly-Vi-Flor
with iron

Essential Vitamins for Infants & Toddlers

MULTIVITAMIN AND FLUORIDE SUPPLEMENT

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.

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

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%	67%
vitamin E	3.35 mg	67%	95%
(as d-alpha-tocopheryl acetate)			
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

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
QAS# 151533-22-1
Distributed by:
Aytu Therapeutics, LLC
Denver, CO 80237
1-855-298-8246
www.aytubio.com



Aytu
BIOPHARMA

PVFD 25+FE061223C1.V1

23594-605-50

Poly-Vi-Flor
with iron

Essential Vitamins for Infants & Toddlers

FRUITY FLAVOR

MULTIVITAMIN AND FLUORIDE SUPPLEMENT

0.25 mg

with iron

NOT SUBSTITUTABLE

CONTAINS:
Arcofolin

Aytu
BIOPHARMA

DYE FREE

GLUTEN FREE

Dispense under a physician's order

1 2/3 FL OZ (50 mL)



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 reach of children.

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
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N) (.ALPHA.-TOCOPHEROL, 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:Q80VPU408O)	FLUORIDE ION	0.25 mg in 1 mL
FERROUS SULFATE (UNII: 39R4TAN1VT) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	7 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
FRUCTOSE (UNII: 6YSS42VSEV)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

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	

