POLY-VITE/IRON ORAL SOLUTION- vitamin a palmitate, sodium ascorbate, cholecalciferol, alpha-tocopherol acetate, thiamine hydrochloride, riboflavin 5-phosphate sodium, niacinamide, pyridoxine hydrochloride, cyanocobalamin, ferrous sulfate solution

Akron Pharma

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# POLY-VITE With IRON Pediatric Drops

Supplement

**Facts** 

Serving size: 1 mL Daily Serving per container: 50

Amount per 1 mL

(dropperful) % Daily Value
Infants through 12 Months of

			illiants through 12 Months of	
age Ch	nildren 1 thr	ough 4 Years of age		
Vitamin A	250 mcg		56%	
33%	_			
Vitamin C	50 mg		143%	
125%	3			
Vitamin D3	10 mcg			
100%	3	100%		
Vitamin E	5 mg			
100%	3	50%		
Thiamin	0.3 mg			
60%	3	43%		
Riboflavin	0.4 mg			
67%	3	50%		
Niacin	4 mg			
50%	3	45%		
Vitamin B6	0.3 mg			
75%		43%		
Vitamin B12	0.5 mg			
25%	0.09	17%		
Iron	11			
mg	_	74%	110%	

POLY-VITE Drops with IRON is designed to help meet the nutritional needs of your growing infant or toddler.\*

POLY-VITE Drops with IRON is an ideal multivitamin supplement during your child's transition to solid foods, during growth spurts, or for the picky eater.

<sup>\*</sup> This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

**Storage:** Store at room temperature 15° -30°C(59° -86°F). Protect from freezing. After opening, store away from direct light. Refrigerator is not required.

WARNING: As with medicine, Keep out of reach of children.

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

### SHAKE WELL BEFORE USE.

#### **Directions for use:**

Administer this supplement using only the device provided. Shake bottle well and fill dropper to 1.0 ml. line. Dosage not to exceed 1.0 ml. per day unless doctor recommends another dosage. Dispense directly into mouth or mixed with formula, fruit juice, cereal, or other foods. Rinse and retain device for further dosing of this product.



Liquid Multivitamin with Iron Supplement for Infants and Toddlers



**Delicious Natural Fruit Flavor** 

1 % fl. oz. (50 mL)

- No Artificial Colors
- Gluten Free
- Alcohol Free

## **Supplement Facts**

Serving size: 1 mL Daily Serving per container: 50

	% Daily Value		
(dropperful) three	Infants through 12 Months of age		
Vitamin A 250 mcg	56%	33%	
Vitamin C 50 mg	143%	125%	
Vilamin D3 10 mcg	100%	100%	
Vitamin E 5 mg	100%	50%	
Thiamin 0.3 mg	60%	43%	
Riboflavin 0.4 mg	67%	50%	
Niacin 4 mg	50%	45%	
Vitamin B6 0.3mg	75%	43%	
Vitamin B12 0.5 mg	25%	17%	
Iron 11 mg	74%	110%	

Usage: As a dietary supplement, take 1ml daily after food or as directed by your Physician.

Storage: Store at room temperature 15°-30°C (59°-86°F). Protect from freezing. After opening, store away from cirect light. Refrigerator is not required. SHAKE WELL BEFORE USE.

DIETARY SUPPLEMENT.

# WARNING: As with medicine, Keep out of reach of children.

Ingredients: Vitamin A Palmitate, Ascorbic Acid,
Vitamin D3, DL Alpha Tocopheryl Acetate, Thiamine
Hydrochloride, Ribofiavin Phosphate Sodium,
Niacinamide, Pyridoxine Hydrochloride,
Cyanocobalamin, Ferrous Sulfate, Sucrose, Glycerol,
Propylene glycol, Polysorbate 80, Methyl Paraben,
Natural Fruit flavor, Citric Acid, Saccharin Sodium,
Disodium edetate, Propyl Paraben, Xanthan gum,
Licuid Caramet, Butylated Hydroxy Anisole,
Butylated Hydroxy Toluene and Purified Water.





## Liquid Multivitamin with Iron Supplement

If you have any questions concerning your child's supplement needs, please consult your child's physician.

The American Academy of Pediatrics (AAP)
recommends using a vitamin D supplement for
exclusively and partially breastfed babies because of
the low average levels of vitamin D in breast milk.

POLY-VITE Drops with IRON is designed to help meet the nutritional needs of your growing infant or toddler.\*

POLY-VITE Drops with IRON is an ideal multivitamin supplement during your child's transition to solid foods, during growth spurts, or for the picky eater.

One daily dose of POLY-VITE Drops with IRON has multi vitamin and Iron with Natural fruit flavored.

POLY-VITE Drops with IRON is gluten-free, lactose-free and contain no artificial colors.

\* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease. WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

# SAVE THIS CARTON FOR FULL LABELING INFORMATION.

Use only with enclosed dropper

#### Directions for use:

Administer this supplement using only the device provided. Shake bottle well and fill dropper to 1.0 ml. line. Dosage not to exceed 1.0 ml. per day unless doctor recommends another dosage. Dispense directly into mouth or mixed with formula, fruit juice, cereal or other foods. Rinse and retain device for further dosing of this product.

Tamper Evident: Do not use if safety seal under cap is broken or missing.

See top flap of the carton for Lot No# and Expiration date. FSSAI Lic. No.: 10017042003338

Manufactured for:





Akron Pharma
373 Route US 46W, Suite 117

Fairfield, NJ 07004 USA. Questions or comments?

Call us toll free: 1-877-225-6999

\*Akron Pharma Inc is not affiliated with the owner of the Trademark POLY.VI.SOL® with iron



## **POLY-VITE/IRON ORAL SOLUTION**

vitamin a palmitate, sodium ascorbate, cholecalciferol, alpha-tocopherol acetate, thiamine hydrochloride, riboflavin 5-phosphate sodium, niacinamide, pyridoxine hydrochloride, cyanocobalamin, ferrous sulfate solution

#### **Product Information**

Product Type DIETARY SUPPLEMENT Item Code (Source) NHRIC:71399-7420

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	.25 mg in 1 mL
SODIUM ASCORBATE (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	50 mg in 1 mL
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	.01 mg in 1 mL
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) (.ALPHATOCOPHEROL - UNII: H4N855PNZ1)	.ALPHA TOCOPHEROL	5 mg in 1 mL
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	.3 mg in 1 mL
RIBOFLAVIN 5'-PHOSPHATE SODIUM (UNII: 20RD1DZH99) (FLAVIN MONONUCLEOTIDE - UNII:7N464URE7E)	FLAVIN MONONUCLEOTIDE	.4 mg in 1 mL
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	4 mg in 1 mL
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII: KV2JZ 1BI6Z)	PYRIDOXINE	.3 mg in 1 mL
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	.5 mg in 1 mL
FERROUS SULFATE (UNII: 39R4TAN1VT) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	11 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
SUCROSE (UNII: C151H8M554)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
POLYSORBATE 80 (UNII: 60ZP39ZG8H)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
PROPYLPARABEN (UNII: Z8IX2SC10H)			
CARAMEL (UNII: T9D99G2B1R)			
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)			
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)			
WATER (UNII: 059QF0KO0R)			
XANTHAN GUM (UNII: TTV12P4NEE)			

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NHRIC:71399-7420-5	50 mL in 1 BOTTLE, DROPPER		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		01/04/2021	

## Labeler - Akron Pharma (067878881)

Revised: 5/2021 Akron Pharma