TRI-VI-FLOR- multivitamin and fluoride supplement suspension/ drops Aytu Therapeutics, LLC

Tri-Vi-Flor

Multivitamin and Fluoride Supplement

Supplement Facts Serving Size 1 mL Dropperful Daily Servings Per Container 50		
<i>g</i>	% Da	ily Value
		Children Under Age 4
Amount Per 1 mL	Infants	Years
Vitamin A (as palmitate) 1125 IU	75%	45%
Vitamin D3 (as cholecalciferol) 300 IU	75%	75%
L-methylfolate Calcium (as Metafolin®) 200 mcg	162%	81%
Fluoride (as sodium fluoride) 0.50 mg	*	*

^{*}U.S. Recommended Daily Allowance has not been established

OTHER INGREDIENTS: Sucrose, water, citric acid, sodium benzoate, potassium sorbate.

Distributed by: Zylera Pharmaceuticals Research Triangle Park, NC 27713

U.S. Patent No. 5,997,915 • U.S. Patent No. 6,254,904

U.S. Patent No. 6,011,040 • U.S. Patent No. 6,441,168

Metafolin® is a registered trademark of Merck KGaA, Darmstadt, Germany *CAS# 151533-22-1

QUESTIONS OR COMMENTS? Please call Zylera Medical Affairs at 1-866-416-9637

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 medicines, keep out of the reach of children.

PRINCIPAL DISPLAY PANEL - Tri-Vi-Flor with 0.5 mg of Fluoride

23594-800-50

Tri-Vi-Flor

Essential Vitamins for Infants & Toddlers

FRUITY FLAVOR

MULTIVITAMIN AND FLUORIDE SUPPLEMENT

0.5 mg

NEW FORMULATION NOT SUBSTITUTABLE

CONTAINS: METAFOLIN

1 2/3 FL OZ (50 mL)

Zylera Pharmaceuticals



TRI-VI-FLOR

multivitamin and fluoride supplement suspension/ drops

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:23594-800
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	1125 [iU] in 50 mL
CHOLECALCIFEROL (UNII: 1C6 V77QF41) (CHOLECALCIFEROL - UNII:1C6 V77QF41)	CHOLECALCIFEROL	300 [iU] in 50 mL
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	200 ug in 50 mL
FLUORIDE ION (UNII: Q80 VPU408O) (FLUORIDE ION - UNII: Q80 VPU408O)	FLUORIDE ION	0.5 mg in 50 mL

Inactive Ingredients		
Ingredient Name	Strength	
SUCROSE (UNII: C151H8 M554)		
WATER (UNII: 059QF0KO0R)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		

Packaging				
#]	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NHRIC:2	3594-800-50	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		09/01/2016	

Supplement Facts		
Serving Size :	Serving per Container :	
Amount Per Serving	% Daily Value	
color		
flavor		

Labeler - Aytu Therapeutics, LLC (117244733)

Revised: 4/2019 Aytu Therapeutics, LLC