

# Frequently Asked Questions



## Poly-Vi-Flor®

(chewable tablet/drops)

### 1 What are Poly-Vi-Flor (PVF) vitamins?

Poly-Vi-Flor vitamins are a combination product of vitamins and fluoride that are available in age-appropriate dosage forms as drops or chewable tablets.

They are prescribed for children to treat or prevent deficiency due to poor diet or low fluoride levels in drinking water and other sources.

### 2 Why is it called PVF?

The name is based on the essential vitamins that make up the product itself.

**Many (Poly) + Vitamin (Vi) + Fluoride (Flor) = Poly-Vi-Flor**

– The “Many” vitamins in Poly-Vi-Flor consist of various essential vitamins such as A, C, D, E, Thiamin (B1), and Folate (B9).

For full list of ingredients, please visit label information on the helpful resource section of the website.

### 3 How many strengths are available for PVF?

Poly-Vi-Flor is available in berry-flavored chewable tablets and fruity-flavored drops.

**Poly-Vi-Flor chewable tablets are available in the following strengths:**

- Multivitamin with 0.5 mg Fluoride
- Multivitamin with 1.0 mg Fluoride

**Poly-Vi-Flor drops are available in the following strengths:**

- Multivitamin with 0.25 mg Fluoride

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

### 4 Is PVF gluten free?

Parents can have peace mind knowing that Poly-Vi-Flor vitamins are:

- Gluten free
- Nut free
- Dye free
- Alcohol free
- Kosher Certified



GLUTEN FREE



NUT FREE MANUFACTURING



DYE FREE



ALCOHOL FREE



KOSHER CERTIFIED

### 5 How many chewable tablets are in each bottle of PVF?

Each bottle contains 30 tablets.

### 6 How many chewable tablets or drops should my child take daily?

Children should take one chewable tablet or 1 mL drop daily.

– Parents should keep medicines out of the reach of children.

To report Suspected Adverse Reactions, contact Aytu Biopharma, Inc. at 1-855-298-8246 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### 7 What is the bottle size of PVF drops?

50 mL bottle.

### 8 How do I administer PVF drops?

**For Poly-Vi-Flor drops, parents should:**

- Shake well before use.
- Administer 1 mL dropperful daily.
- Drops may be dispensed directly into the mouth.
- Drops also may be mixed with formula, fruit juice, cereal, or other foods.
- After opening, store away from direct sunlight.

This product is not intended to diagnose, treat, cure, or prevent any disease. These statements have not been evaluated by the FDA.

Caution: Poly-Vi-Flor chewable tablets are not recommended for children under the age of 4 due to the risk of choking. Tablets should be chewed.

Do not exceed the suggested dose. Dental fluorosis may result by taking too much fluoride over a long period when the teeth are forming under the gums. Only children aged 8 years and younger are at risk because this is when permanent teeth are developing. Children older than 8 years, adolescents, and adults cannot develop dental fluorosis.

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### 9 Do PVF drops require refrigeration?

No. The drops do not require refrigeration. After opening, store away from direct sunlight.

### 10 What is dental fluorosis?

Dental fluorosis is a condition that causes changes in the appearance of tooth enamel.<sup>1</sup> It may result when children regularly consume fluoride during the teeth-forming years, age 8 and younger.<sup>1</sup> Most dental fluorosis in the U.S. is mild, appearing as white spots on the tooth surface, and does not affect dental function.

Fluoride supplements can be prescribed for children at high risk for tooth decay and whose primary source of drinking water has a low fluoride level. If the children are younger than 6 years, the dentist or physician should weigh the risks for developing decay without supplements with the possibility of developing dental fluorosis.<sup>1</sup>

Visit Centers for Disease control website for more information: [https://www.cdc.gov/fluoridation/faqs/dental\\_fluorosis/index.htm](https://www.cdc.gov/fluoridation/faqs/dental_fluorosis/index.htm).

### 11 What are the inactive ingredients in PVF vitamins?

#### Poly-Vi-Flor Chewable Tablets:

- Inactive ingredients: sucrose, sorbitol, fructose, citric acid, beet root juice, raspberry flavor, grape flavor, stearic acid, carrageenan, cherry flavor, magnesium stearate, and sucralose.

#### Poly-Vi-Flor Drops:

- Inactive ingredients: glycerin, water, fructose, ascorbic acid, polysorbate 80, natural flavoring, soy lecithin, and potassium sorbate.

Reference: 1. CDC website. [www.cdc.gov/fluoridation/faqs/dental\\_fluorosis/index.htm](http://www.cdc.gov/fluoridation/faqs/dental_fluorosis/index.htm).



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### 12 How much does PVF cost?

Poly-Vi-Flor vitamins are currently only available from an RxConnect pharmacy. Pharmacy locations are throughout NY, NJ, and PA.

For eligible patients with commercial insurance, you'll pay \$10 or less through one of our RxConnect pharmacies. Please visit the website, click the 'order now' button and follow the instructions to complete your purchase.

### 13 What if my child has allergies?

Poly-Vi-Flor vitamins contain fish oil and soy. Children with these allergies should not take Poly-Vi-Flor vitamins. Parents should consult their healthcare professional for more information.

For full list of ingredients, please visit label information on the helpful resource section of the website.

### 14 Should my child stop taking their over-the-counter (OTC) vitamin if they start taking PVF?

Parents should consult their healthcare professional for questions regarding OTC vitamins. For a full list of ingredients, please visit the helpful resource section of the website.

Keep out of reach of children. In case of accidental overdose, seek professional emergency assistance (911) or contact the Poison Control Center immediately (1-800-222-1222).

Poly-Vi-Flor should not be used by patients with a known history of hypersensitivity to any of the listed ingredients.

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