Important Considerations When Using Dosage Schedule:

- The amount of sodium fluoride in the 50 mL size is well below the maximum to be dispensed at one time according to recommendations of the American Dental Association.

When prescribing vitamin fluoride products:

- The suggested dose should not be exceeded since dental fluorosis may result from continued ingestion of large amounts of fluoride.

**PRECAUTIONS**

- The reaction may be expressed by the equation:

\[
\text{Ca}_{10} \text{(PO}_4\text{)}_3 \text{(OH)}_2 + 2F^- \rightarrow \text{Ca}_{10} \text{(PO}_4\text{)}_3 \text{F}_2 + 2OH^- \\
(\text{Hydroxyapatite}) \\
(\text{Fluorapatite})
\]

- Three stages of fluoride deposition in tooth enamel can be distinguished:
  1. Small amounts (reflecting the low levels of fluoride in tissue fluids) are incorporated into the enamel crystals while they are being formed.
  2. After enamel has been laid down, fluoride deposition continues in the surface enamel. Diffusion of fluoride from the surface inward is apparently restricted.
  3. After eruption, the surface enamel acquires fluoride from water, food, supplementary fluoride and smaller amounts from saliva.

**INDICATIONS AND USAGE**

- Supplementation of the diet with vitamins A, C and D.
- Multi-Vitamin Drops with Fluoride and Iron 0.25 mg also provides fluoride for caries prophylaxis.

The American Academy of Pediatrics recommends that children up to age 16, in areas where the drinking water contains less than optimal levels of fluoride, receive daily fluoride supplementation.

The American Academy of Pediatrics recommend that infants and young children 6 months to 3 years of age, in areas where the drinking water contains less than 0.3 ppm of fluoride, and children 3-6 years of age, in areas where the drinking water contains 0.3 through 0.6 ppm of fluoride, receive 0.25 mg of supplemental fluoride daily which is provided in a dose of 1 mL of Multi-Vitamin Drops with Fluoride 0.25 mg (See Dosage and Administration).

Multi-Vitamin Drops with Fluoride and Iron 0.25 mg supply significant amounts of vitamin A, C and D to supplement the diet, and to help assure that nutritional deficiencies of these vitamins will not develop.

Thus, in a single easy-to-use preparation, children obtain essential vitamins and fluoride.

**WARNINGS**

- As in the case of all medications, keep out of reach of children.

**DISCLAIMER**

- This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

---

**Multi-Vitamin Drops with Fluoride and Iron 0.25 mg**

**Supplemental Facts**

<table>
<thead>
<tr>
<th>Each 1.0 mL supplies:</th>
<th>Percentage of U.S. Recommended Daily Allowance</th>
<th>Children 6 mos to 4 Years old</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A (as Vitamin A Palmitate)</td>
<td>1500 IU</td>
<td>60%</td>
</tr>
<tr>
<td>Vitamin C (as Ascorbic Acid)</td>
<td>35 mg</td>
<td>88%</td>
</tr>
<tr>
<td>Vitamin D (as Cholecalciferol)</td>
<td>400 IU</td>
<td>100%</td>
</tr>
<tr>
<td>Vitamin E (as D-Alpha-Tocopheryl Acid Saccinate)</td>
<td>5 IU</td>
<td>50%</td>
</tr>
<tr>
<td>Vitamin B1 (as Thiamine HCl)</td>
<td>0.5 mg</td>
<td>71%</td>
</tr>
<tr>
<td>Vitamin B2 (as Riboflavin Phosphate Sodium)</td>
<td>0.56 mg</td>
<td>75%</td>
</tr>
<tr>
<td>Niacin (as Niacinamide)</td>
<td>8 mg</td>
<td>89%</td>
</tr>
<tr>
<td>Vitamin B6 (as Pyridoxine HCl)</td>
<td>0.4 mg</td>
<td>57%</td>
</tr>
<tr>
<td>Iron (as Ferrous Sulfate)</td>
<td>10 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Fluoride (as Sodium Fluoride)</td>
<td>0.25 mg</td>
<td>*</td>
</tr>
</tbody>
</table>

*Daily Value not established.

See INDICATIONS AND USAGE section for use by children 6 months to 6 years of age.

This product does not contain the essential vitamin folic acid.

Active ingredient for caries prophylaxis: Fluoride as sodium fluoride. This product does not contain Folic Acid.

Other ingredients: Cherry Flavor, Citric Acid Anhydrous, Glycerin, Orange Flavor, Potassium Sorbate, Propylene Glycol, Purified Water, Sodium Benzoate, Sorbitol Solution, Sucralose.

**CLINICAL PHARMACOLOGY**

- It is well established that fluoridation of the water supply (1 ppm fluoride) during the period of tooth development leads to a significant decrease in the incidence of dental caries.

Hydroxyapatite is the principal crystal for all calcified tissue in the human body. The fluoride ion reacts with hydroxyapatite in the tooth as it is formed to produce the more caries-resistant crystal, fluorapatite.

- Thus, in a single easy-to-use preparation, children obtain essential vitamins and fluoride.
All sources of fluoride should be evaluated with a thorough fluoride history. Patient exposure to multiple water sources can make proper prescribing complex.

Ingestion of higher than recommended levels of fluoride by children has been associated with an increase in mild dental fluorosis in developing, unerupted teeth.

Fluoride supplements require long-term compliance on a daily basis.

ADVERSE REACTIONS

Allergic rash and other idiosyncrasies have been rarely reported.

DOSEAGE AND ADMINISTRATION:

See following chart. May be dropped directly into the mouth with dropper; or mixed with cereal, fruit juice or other food.

<table>
<thead>
<tr>
<th>Fluoride Ion Level in Drinking Water (ppm)*</th>
<th>&lt;0.3 ppm</th>
<th>0.3 - 0.6 ppm</th>
<th>&gt;0.6 ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth - 6 months</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>6 mos - 3 years</td>
<td>0.25 mg (1 mL) / day†</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>3 - 6 years</td>
<td>0.50 mg (2 mL) / day</td>
<td>0.25 mg (1 mL) / day</td>
<td>None</td>
</tr>
</tbody>
</table>

* 1.0 ppm = 1 mg/liter
† 2.2 mg sodium fluoride contains 1 mg fluoride ion.

HOW SUPPLIED

Multi-Vitamin and Fluoride and Iron 0.25 mg drops is available in 50 mL bottles with accompanying calibrated dropper.

RECOMMENDED STORAGE

Store at controlled room temperature 15°-25°C (between 59°F and 77°F). Excursions Permitted. After opening store away from direct light. Close tightly after each use. Occasional deepening of color has no significant effect on vitamin potency.

REFRIGERATION IS NOT REQUIRED.

SHAKE WELL.

REFERENCES

3. American Dental Association Council on Dental Therapeutics: Accepted Dental Therapeutics, ed 38, Chicago, 1979, p321.

Distributed by:
Method Pharmaceuticals, LLC
Fort Worth, TX 76118
877-250-3427
Rev. 01/17
Made in the USA

PRINCIPAL DISPLAY PANEL

NDC 58657-327-50
Multi-Vitamin
Drops
With Fluoride & Iron
0.25 mg
1.69 FL. OZ. (50 mL)
Rx Only
## Product Information

**Product Type**: Human Prescription Drug  
**Item Code (Source)**: NDC: 58657-327

**Route of Administration**: Oral

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vitamin A Palmitate</strong></td>
<td>Vitamin A</td>
<td>1500 [iU] in 1 mL</td>
</tr>
<tr>
<td><strong>Ascorbic Acid</strong></td>
<td>Ascorbic Acid</td>
<td>35 mg in 1 mL</td>
</tr>
<tr>
<td><strong>Cholecalciferol</strong></td>
<td>Cholecalciferol</td>
<td>400 [iU] in 1 mL</td>
</tr>
<tr>
<td><strong>Alpha-Tocopherol Succinate, D-</strong></td>
<td>Alpha-Tocopherol Succinate, D-</td>
<td>5 [iU] in 1 mL</td>
</tr>
<tr>
<td><strong>Thiamine Hydrochloride</strong></td>
<td>Thiamine</td>
<td>0.5 mg in 1 mL</td>
</tr>
<tr>
<td><strong>Riboflavin 5-Phosphate Sodium</strong></td>
<td>Riboflavin 5-Phosphate Sodium</td>
<td>0.6 mg in 1 mL</td>
</tr>
<tr>
<td><strong>Pyridoxine Hydrochloride</strong></td>
<td>Pyridoxine Hydrochloride</td>
<td>0.4 mg in 1 mL</td>
</tr>
<tr>
<td><strong>Sodium Fluoride</strong></td>
<td>Fluoride Ion</td>
<td>0.25 mg in 1 mL</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anhydrous Citric Acid</td>
<td></td>
</tr>
</tbody>
</table>
Potassium Sorbate |  
Propylene Glycol |  
Sodium Benzoate |  
Sorbitol |  
Sucralose |  

### Product Characteristics

- **Color**: Cherry, Orange
- **Shape**: Imprint Code
- **Flavor**: Cherry, Orange
- **Contains**: Imprint Code
### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:58657-327-50</td>
<td>1 in 1 BOX</td>
<td>02/24/2017</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>50 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product</td>
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</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNAPPROVED DRUG OTHER</td>
<td></td>
<td>02/24/2017</td>
<td></td>
</tr>
</tbody>
</table>

**Labeler**: Method Pharmaceuticals, LLC (060216698)