

**MULTIVITAMIN WITH FLUORIDE- vitamin a acetate, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, and sodium fluoride tablet, chewable**  
**H2-Pharma, LLC**

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**MultiVitamin with Fluoride Chewable Tablets**

**DOSAGE AND ADMINISTRATION**

One tablet daily or as directed by a physician.

| <b>Supplement Facts</b>           |                           |                      |
|-----------------------------------|---------------------------|----------------------|
| <b>Serving Size 1 Tablet</b>      |                           |                      |
| <b>Servings Per Container 100</b> |                           |                      |
|                                   | <b>Amount Per Serving</b> | <b>% Daily Value</b> |
| Vitamin A                         | 2500 IU                   | 50%                  |
| Vitamin C                         | 60 mg                     | 100%                 |
| Vitamin D                         | 400 IU                    | 100%                 |
| Vitamin E                         | 15 IU                     | 50%                  |
| Thiamine                          | 1.05 mg                   | 70%                  |
| Riboflavin                        | 1.2 mg                    | 70%                  |
| Niacinamide                       | 13.5 mg                   | 68%                  |
| Vitamin B <sub>6</sub>            | 1.05 mg                   | 53%                  |
| Folic Acid                        | 0.3 mg                    | 75%                  |
| Vitamin B <sub>12</sub>           | 4.5 mcg                   | 75%                  |
| Fluoride                          | 0.5 mg                    | *                    |

\* Daily Value not established

**WARNING**

**KEEP OUT OF THE REACH OF CHILDREN.**

In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Other Ingredients: Artificial cherry flavor, artificial grape flavor, ascorbic acid, cholecalciferol, compressible sugar, D&C Red #7 calcium lake, FD&C Blue #1 aluminum lake, FD&C Yellow #6 aluminum lake, folic acid, magnesium stearate, microcrystalline cellulose, natural and artificial orange flavor, niacinamide, polyethylene glycol, pyridoxine HCl, riboflavin, sodium ascorbate, sodium fluoride, stearic acid, sucralose, thiamine HCl, vitamin A acetate, vitamin B12 and vitamin E acetate.

**Active ingredient for caries prophylaxis:** Fluoride as sodium fluoride.

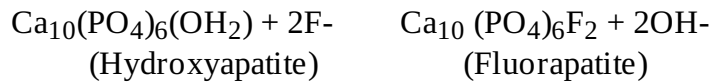
**CLINICAL PHARMACOLOGY**

Significant decrease in the incidence of dental caries can be linked to the fluoridation of the water supply (1ppm fluoride) during the period of tooth development.

**MultiVitamin with Fluoride Chewable Tablets** provide sodium fluoride and ten essential vitamins in a chewable tablet. Because the tablets are chewable, they provide a topical as well as systemic source of

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

The reaction may be expressed by the equation:



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 the water, food, supplementary fluoride and smaller amounts of saliva.

## DIETARY SUPPLEMENTATION

Multivitamins with fluoride offer supplementation of the diet with 10 vitamins and fluoride.

## WARNINGS

**AS IN THE CASE OF ALL MEDICATIONS, KEEP OUT OF THE REACH OF CHILDREN.**

This tablet should be chewed. This product, as with all chewable tablets are not recommended for children under the age of 4 due to risk of choking.

## PRECAUTIONS

The suggested dose of **MultiVitamin with Fluoride Chewable Tablets** should not be exceeded, since dental fluorosis may result from continued ingestion of large amounts of fluoride.

Before recommending **MultiVitamin with Fluoride Chewable Tablets**

1. Determine the fluoride content of the drinking water from all major sources
2. Make sure the child is not receiving significant amounts of fluoride from other sources such as medications and swallowed toothpaste
3. Periodically check to make sure that the child does not develop significant dental fluorosis.

## ADVERSE REACTIONS

Allergic rash and other idiosyncrasies have been rarely reported.

**To report SUSPECTED ADVERSE REACTIONS, contact H2-Pharma, LLC at 1 (866) 592-6438 or FDA at 1 (800) 332-1088 or via the web at [www.fda.gov/medwatch/index.html](http://www.fda.gov/medwatch/index.html) for voluntary reporting of adverse reactions.**

## DOSAGE AND ADMINISTRATION

One tablet daily or as directed by a physician.

## HOW SUPPLIED

**MultiVitamin with Fluoride Chewable Tablets** 0.25 mg are available as orange, red and purple chewable tablets imprinted with "151" in 100 tablet bottles.

**MultiVitamin with Fluoride Chewable Tablets** 0.5 mg are available as orange, red and purple chewable tablets imprinted with "152" in 100 tablet bottles.

**MultiVitamin with Fluoride Chewable Tablets** 1.0 mg are available as orange, red and purple chewable tablets imprinted with "153" in 100 tablet bottles.

## STORAGE

Store at controlled room temperature 20°C-25°C (68°-77°F), excursions permitted between 15°-30°C (59°-86°F) [See USP].

Distributed by:

**H2-Pharma, LLC**  
2010 Berry Chase Place  
Montgomery, AL 36117  
www.h2-pharma.com  
1067085

## PRINCIPAL DISPLAY PANEL - 0.5 mg Tablet Bottle Label

61269-152-01

MultiVitamin  
with Fluoride  
Chewable Tablets

0.5 mg  
MultiVitamin and Fluoride Supplement

Dietary Supplement

100 Tablets

H<sup>2</sup>pharma

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61269-152-01

# MultiVitamin

with Fluoride  
**Chewable Tablets**

**0.5 mg**  
**MultiVitamin and Fluoride Supplement**

Dietary Supplement

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61269-15201

6



**PEEL HERE**

## MULTIVITAMIN WITH FLUORIDE

vitamin a acetate, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, and sodium fluoride tablet, chewable

## Product Information

|                         |                    |                    |                 |
|-------------------------|--------------------|--------------------|-----------------|
| Product Type            | DIETARY SUPPLEMENT | Item Code (Source) | NHRIC:61269-152 |
| Route of Administration | ORAL               |                    |                 |

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength          | Strength  |
|--|----------------------------|-----------|
| VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)                   | VITAMIN A                  | 2500 [iU] |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)                   | ASCORBIC ACID              | 60 mg     |
| CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)               | CHOLECALCIFEROL            | 400 [iU]  |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1) | .ALPHA.-TOCOPHEROL ACETATE | 15 [iU]   |
| THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)           | THIAMINE HYDROCHLORIDE     | 1.05 mg   |
| RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)                         | RIBOFLAVIN                 | 1.2 mg    |
| NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)                       | NIACINAMIDE                | 13.5 mg   |
| PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)           | PYRIDOXINE HYDROCHLORIDE   | 1.05 mg   |
| FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)                         | FOLIC ACID                 | 0.3 mg    |
| CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)                 | CYANOCOBALAMIN             | 4.5 ug    |
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)                  | FLUORIDE ION               | 0.5 mg    |

## Inactive Ingredients

| Ingredient Name                                     | Strength |
|---|----------|
| CHERRY (UNII: BUC5I9595W)                           |          |
| GRAPE (UNII: 6X543N684K)                            |          |
| SUCROSE (UNII: C151H8M554)                          |          |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)                    |          |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                  |          |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8)                |          |
| MAGNESIUM STEARATE (UNII: 70097M6I30)               |          |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)       |          |
| ORANGE (UNII: 5EVU04N5QU)                           |          |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |          |
| SODIUM ASCORBATE (UNII: S033EH8359)                 |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)                     |          |
| SUCRALOSE (UNII: 96K6UQ3ZD4)                        |          |

## Packaging

| # | Item Code          | Package Description | Marketing Start Date | Marketing End Date |
|---|--------------------|---------------------|----------------------|--------------------|
| 1 | NHRIC:61269-152-01 | 100 in 1 BOTTLE     |                      |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| DIETARY SUPPLEMENT |  | 12/05/2016           |                    |

## Supplement Facts

Serving Size :

Serving per Container :

|                    | Amount Per Serving | % Daily Value |
|--------------------|--------------------|---------------|
| color              |                    |               |
| color              |                    |               |
| color              |                    |               |
| scoring            | 1                  |               |
| shape              |                    |               |
| size (solid drugs) | 13 mm              |               |
| imprint            |                    |               |
| flavor             |                    |               |
| flavor             |                    |               |
| flavor             |                    |               |

**Labeler** - H2-Pharma, LLC (028473634)

Revised: 2/2020

H2-Pharma, LLC