

**MULTIVITAMIN WITH FLUORIDE- sodium fluoride tablet, chewable
A-S Medication Solutions**

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.

Multivitamin with Fluoride 1.0 mg

Prescribing Information

MULTIVITAMIN WITH FLUORIDE vitamin A, ascorbic acid, sodium ascorbate, cholecalciferol, alpha-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid and cyanocobalamin tablet, chewable

Each Fluoride Chewable Tablet Contains:

Supplement Facts

Dosage Size 1 Chewable Tablet

Amount per tablet 1.0 mg %DV Adults and Children 4 years or More

Vitamin A 750 ug 50%

Vitamin C 60 mg 100%

Vitamin D 10 ug 100%

Vitamin E 13 mg 50%

Thiamine 1.05 mg 70%

Riboflavin 1.2 mg 71%

Niacin 13.5 mg 68%

Vitamin B₆ 1.05 mg 53%

Folate 300 ug 75%

Vitamin B₁₂ 4.5 ug 75%

Fluoride 1.0 mg *

*daily value (DV) not established

Multivitamin with Fluoride 1 mg active ingredient for caries prophylaxis: Fluoride as sodium fluoride

Multivitamin with 1 mg Fluoride Chewable Tablets

provide sodium fluoride and ten essential vitamins in a chewable tablet.

Other ingredients: ascorbic acid, cholecalciferol, compressible sugar, croscarmellose

sodium, dl-alpha tocopheryl acetate, D and C Red #27 aluminum lake, FD and C Blue #1 aluminum lake, folic acid, grape flavor, magnesium stearate, microcrystalline cellulose, niacinamide, pyridoxine, riboflavin, sodium ascorbate, stearic acid, thiamine, vitamin A, vitamin B 12.

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.

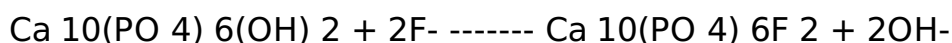
Multivitamin with 1.0 mg Fluoride Chewable Tablets provide sodium fluoride and ten essential vitamins in a chewable tablet. Because the tablets are chewable, they provide a topical as well as systemic source of fluoride.

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:



(Hydroxyapatite) (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 the water, food, supplementary fluoride and smaller amounts from saliva.

INDICATIONS AND USAGE

Supplementation of the diet with ten essential vitamins.

Supplementation of the diet with fluoride for caries prophylaxis.

Multivitamin with 1.0 mg Fluoride Chewable Tablets

provide 1.0 mg fluoride in tablet form for children 6-16 years of age in areas where the water fluoride level is less than 0.3 ppm.

Multivitamin with 1.0 mg Fluoride Chewable Tablets

supply significant amounts of Vitamins A, C, D, E, thiamine, riboflavin, niacin, vitamin B 6, vitamin B 12, and folate 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 ten essential vitamins and the important mineral, fluoride.

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

Children using

Multivitamin with 1.0 mg Fluoride Chewable Tablets

regularly should receive semiannual dental examinations. The regular brushing of teeth and attention to good oral hygiene practices are also essential.

Multivitamin with Fluoride Chewable Tablets is a prescription product for the clinical dietary management of the metabolic processes of caries prophylaxis and provides supplementation of the diet with ten essential vitamins.

WARNING

Keep out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Caution: Do not eat or drink dairy products within one hour of fluoride administration.

Should be chewed. This product, as all chewable tablets, is not recommended for children under age 4 due to risk of choking.

PRECAUTION

The suggested dose of

Multivitamin with 1.0 mg Fluoride Chewable Tablets

should not be exceeded, since dental fluorosis may result from continued ingestion of large amounts of fluoride.

Before prescribing

Multivitamin with 1.0 mg 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.

DOSAGE AND ADMINISTRATION

One tablet daily, to be dissolved in the mouth or chewed before swallowing. Do not give a chewable tablet to a child younger than 4 years old.

HOW SUPPLIED

Product: 50090-4475

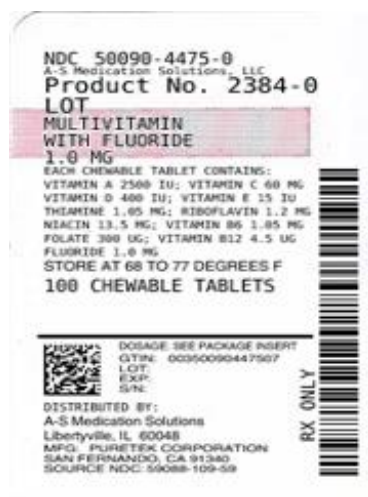
NDC: 50090-4475-0 100 TABLET, CHEWABLE in a BOTTLE, PLASTIC

STORAGE

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F). See USP Controlled Room Temperature.

Dispense in a tight, light resistant container with a child-resistant closure as defined in the USP/NF. All prescription substitutions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product.

Sodium Fluoride



MULTIVITAMIN WITH FLUORIDE

sodium fluoride tablet, chewable

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50090-4475(NDC:59088-109)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	1 mg
VITAMIN A (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	750 ug
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	24 mg
SODIUM ASCORBATE (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	36 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	13.5 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.05 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.2 mg
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	13.5 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	1.05 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	300 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4.5 ug

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ASPARTAME (UNII: Z0H242BBR1)	

Product Characteristics

Color	purple (Dark purple)	Score	no score
Shape	ROUND	Size	13mm
Flavor	GRAPE (Grape flavor)	Imprint Code	109
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-4475-0	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/23/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/01/2011	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-4475)

Revised: 3/2021

A-S Medication Solutions