

DAVIMET- multivitamin tablet, chewable
PureTek Corporation

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](#).

Davimet
Multivitamin Chewable Tablets

Each Chewable Tablet Contains:

Vitamin A (as retinyl acetate).....	750 mcg RAE
Vitamin C (as sodium ascorbate & ascorbic acid).....	60 mg
Vitamin D3 (as cholecalciferol).....	10 mcg
Vitamin E	10 mg
Thiamin (as thiamine mononitrate).....	1.05 mg
Riboflavin.....	1.2 mg
Niacin (as niacinamide).....	13.5 mg
Vitamin B6 (as pyridoxine hydrochloride).....	1.05 mg
Folate (as folic acid).....	1667 mcg DFE (1000 mcg folic acid)
Vitamin B12 (as cyanocobalamin).....	4.5 mcg

Other Ingredients:

Aspartame, Croscarmellose Sodium, Grape Flavor, Magnesium Stearate (vegetable source), Microcrystalline Cellulose, Stearic Acid (vegetable source), Sucrose, CI 45410 (Red 27 Lake), CI 42090 (FD&C Blue No. 1 Aluminum Lake).

Phenylketonurics: Phenylalanine 3.0 mg Per Tablet.

INDICATIONS AND USAGE

Davimet™ Multivitamin Chewable Tablets is indicated to provide significant amounts of Vitamins A, C, D, E, thiamine, riboflavin, niacin, vitamin B6, vitamin B12, and folate to supplement the diet, and to help assure that nutritional deficiencies of these vitamins will not develop. Expressly formulated to provide essential nutrients, tailored to the needs of all individuals ages 4 years old and above, promoting overall health, energy, and vitality.

Contraindications:

This product is contraindicated in patients with known hypersensitivity to any of its ingredients.

WARNING

Keep out of the reach of children. In case of accidental overdose, seek

professional assistance or contact a Poison Control Center immediately.

CAUTION: Should be chewed.

PRECAUTIONS

Folic acid in doses above 0.1 mg daily may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations remain progressive. There is a potential danger in administering folic acid to patients with undiagnosed anemia, since folic acid may obscure the diagnosis of pernicious anemia by alleviating the hematologic manifestations of the disease while allowing the neurologic complications to progress. This may result in severe nervous system damage before the correct diagnosis is made. Adequate doses of vitamin B12 may prevent, halt, or improve the neurologic changes caused by pernicious anemia.

The patient's medical conditions and consumption of other drugs, herbs, and/or supplements should be considered.

For use on the order of a healthcare practitioner. Call your doctor about side effects. To report side effects, call **PureTek Corporation at 1-877-921-7873 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Adverse Reactions:

Folic Acid: Allergic sensitizations has been reported following both oral and parenteral administration of folic acid. Adverse reactions have been reported with specific vitamins and minerals but generally at levels substantially higher than those contained herein. However, allergic and idiosyncratic reactions are possible at lower levels.

DOSAGE AND ADMINISTRATION

One tablet daily, to be dissolved in the mouth or chewed before swallowing.

HOW SUPPLIED

Multivitamin chewable tablets are light purple with speckles, grape flavor, un-scored, round tablets. Available on prescription only in bottles of 30 tablets – NDC 59088-695-54. 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.

STORAGE

Do not use if bottle seal is broken. KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Store at controlled room temperature 20° to 25°C (68° to 77°F). [See USP].

DAVIMET

multivitamin tablet, chewable

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:59088-695
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
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-	10 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)		PYRIDOXINE	1.05 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
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)		FOLIC ACID	1667 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)		CYANOCOBALAMIN	4.5 ug

Inactive Ingredients				
Ingredient Name			Strength	
SUCROSE (UNII: C151H8M554)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
D&C RED NO. 27 (UNII: 2LRS185U6K)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
ASPARTAME (UNII: Z0H242BBR1)				
Product Characteristics				
Color	purple (Light Purple)	Score	no score	
Shape	ROUND	Size	13mm	
Flavor	GRAPE (Grape flavor)	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-695-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/19/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
unapproved drug other			09/19/2022	

Labeler - PureTek Corporation (785961046)