DAVIMET-M- 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-M

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 (as DL-Alpha Tocopheryl Acetate)	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 L-5-Methyltetrahydrofolate calcium salt)	1700 mcg DFE
(1000 mcg as L-5-Methylfolate)	
Vitamin B12 (as Methylcobalamin)	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-M™ 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.

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

Folate 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 folate to patients with undiagnosed anemia, since folate 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.

Use only under the direction of a licensed 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:

Folate: Allergic sensitizations has been reported following both oral and parenteral administration of folate. 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 bottle of 30 tablets – NDC 59088-158-54. 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 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Davimet-M™

Manufactured in the USA by:

PureTek Corporation

Panorama City, CA 91402 Questions? Call toll-free:

1-877-921-7873



Davimet-M™ Multivitamin Chewable Tablets provide ten essential vitamins in a chewable tablet.

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List No: 15854IFA Rev. No: 38848

Active Ingredient/Active Moiety

NIACIN (UNII: 2679MF687A) (NIACIN - UNII: 2679MF687A)

LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID -

METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)



Supplement Serving Size: Servings per container:		Tablet 30
Amount Pe	r Serving	%DV
Vitamin A (as Retinyl Acetate) 750	mcg RAE	83%
Vitamin C (as Sodium Ascorbate & Ascorbic Acid)	60 mg	67%
Vitamin D ₃ (as Cholecalciferol)	10 mcg	50%
Vitamin E (as DL-Alpha Tocopheryl Acetate)	10 mg	67%
Thiamin (as Thiamine Mononitrate)	1.05 mg	88%
Riboflavin	1.2 mg	92%
Niacin (as Niacinamide)	13.5 mg	84%
Vitamin B ₆ (as Pyridoxine Hydrochloride)	1.05 mg	62%
Folate (as L-5-Methyltetrahydrofolate calcium salt) 1700 mcg DFE 417%		
(1000 mcg as L-5-Methylfolate)		ylfolate)
Vitamin B ₁₂ (as Methylcobalamin)	4.5 mcg	188%

DERMACINE:

Davimet-M

Multivitamin
Chewable Tablets

Grape Flavor

30 Tablets

DAVIMET-M

UNII:8S95DH25XC)

multivitamin tablet, chewable

Product Information

	Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:59088-158
l	Route of Administration	ORAL		

Ingredient Name	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
.ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHATOCOPHEROL, DL UNII:7QWA1RIO01)	.ALPHA TOCOPHEROL, DL-	10 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII: KV2JZ 1BI6Z)	PYRIDOXINE	1.05 mg
THIAMINE MONONITRATE (UNII: 8K0104919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.05 mg
RIBOFLAVIN (UNII: TLM29760FR) (RIBOFLAVIN - UNII:TLM29760FR)	RIBOFLAVIN	1.2 mg

NIACIN

CALCIUM

LEVOMEFOLATE

METHYLCOBALAMIN

13.5 mg

1000 ug

4.5 ug

Inactive Ingredients	
Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	

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- 158-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/30/2023	

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Labeler - PureTek Corporation (785961046)

Revised: 11/2023 PureTek Corporation