

## **MENATROL- folate, multivitamin capsule**

### **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.*

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## **Menatrol**

### **DESCRIPTION:**

#### **Full Prescribing Information:**

##### **Drug Description:**

**Menatrol™** Capsules are a comprehensive dietary supplement tailored for individuals undergoing menopause. This specialized formulation offers a blend of vitamins, minerals, and plant extracts aiming to alleviate common menopausal symptoms:

**Vitamin D3 (Cholecalciferol):** Contained in a dose of 15 mcg (600 IU), Vitamin D3 plays a pivotal role in maintaining bone health and may also help mitigate mood disturbances. It is recommended to seek a supplement offering 600-800 IU of Vitamin D3 daily, although personal dosing should be discussed with a licensed healthcare practitioner.

**Vitamin B6 (Pyridoxine Hydrochloride):** At a dosage of 1.5 mg, Vitamin B6 is integral for mood stabilization and promoting energy. Typically, adults are advised to consume 1.3-2.0 mg per day. Always refer to the supplement label for specific dosages.

**Folate (L-5-Methyltetrahydrofolate calcium salt):** Provided in a measure of 1700 mcg DFE (with 1000 mcg as L-5-Methylfolate), folate is pivotal for holistic health, potentially aiding in mood enhancement and energy regulation. An average adult dosage is between 400-800 mcg daily.

**Calcium (Calcium Carbonate):** At a concentration of 220 mg, calcium is a key mineral that fortifies bones, particularly crucial during menopause due to heightened osteoporosis risks. Women over 50 typically require around 1000-1300 mg of calcium daily, although intake should be calibrated based on diet.

**Magnesium (Magnesium Oxide):** Present in an amount of 100 mg, magnesium offers relief from muscle cramps, mood fluctuations, and sleep disturbances. On average, adults are recommended to consume 300-400 mg per day, though individual requirements can differ.

**Rhapontic Rhubarb:** Rhapontic rhubarb (*Rheum rhaponticum*) is a natural ingredient that some women use to address menopausal symptoms, including hot flashes and mood swings. The appropriate dosage for this specific ingredient may vary, so consult the product label or a licensed healthcare practitioner for guidance.

#### **Each capsule contains:**

Vitamin D3 (as Cholecalciferol).....	15 mcg (600 IU)
Vitamin B6 (as Pyridoxine Hydrochloride).....	1.5 mg
Folate (as L-5-Methyltetrahydrofolate calcium salt).....	1700 mcg DFE (1000 mcg as L-5-Methylfolate)
Calcium (as Calcium Carbonate).....	220 mg
Magnesium (as Magnesium Oxide).....	100 mg
Rhapontic Rhubarb (Siberian Rhubarb) Root Extract...	4 mg

**Other Ingredients:**

DL-Alpha Tocopheryl Acetate, Magnesium Stearate, Microcrystalline Cellulose, Vegetable Capsule.

**Indications and Usage:**

For the dietary management of menopausal symptoms and the support of overall health during the menopausal phase.

**Contraindications:**

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. **Menatrol™ Capsules** are contraindicated in patients with hypercalcemia, malabsorption syndrome, abnormal sensitivity to the toxic effects of vitamin D, and hypervitaminosis D.

**Warnings:**

Tell your doctor if you have: kidney problems, thyroid disease. This medication should be used as directed during pregnancy or while breast-feeding. Consult your doctor. Administration of folate alone is improper therapy for pernicious anemia and other megaloblastic anemias in which vitamin B12 is deficient.

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

**Adverse Reactions:**

Possible side effects may include gastrointestinal upset. If any side effects persist or worsen, discontinue use and consult a physician.

**Drug Interactions:**

Consult with a licensed healthcare practitioner before use if taking prescription medications, especially those affecting bone health or hormonal therapies.

**Pregnancy and Lactation:**

Not recommended for use during pregnancy or lactation without consulting with a licensed healthcare practitioner.

### **Overdosage:**

In case of overdose, seek medical attention immediately. Symptoms may include nausea, vomiting, or diarrhea.

### **Clinical Pharmacology:**

The ingredients in this formulation work synergistically to potentially alleviate various menopausal symptoms by supporting bone health, mood regulation, and overall wellness.

### **Nonclinical Toxicology:**

There are no known toxicities associated with the recommended doses of the ingredients in this supplement.

### **Clinical Studies:**

Several ingredients in this supplement have been clinically studied for their effectiveness in managing menopausal symptoms, including bone health, mood disturbances, and overall well-being.

### **Dosage and Administration:**

Take one (1) capsule daily or as directed by a licensed healthcare practitioner.

### **How Supplied:**

**Menatrol™ Capsules** are light yellow powder with black specks, encased in a hard shell capsule. They are packaged in bottle containing 30 capsules – NDC 59088-156-54. Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure.

### **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]. Protect from light and moisture and avoid excessive heat.

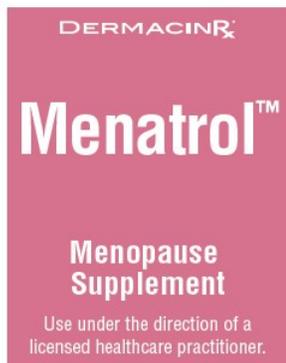
**Menatrol™**

**Manufactured in the USA by:**

**PureTek Corporation**  
Panorama City, CA 91402  
For questions or information  
call toll-free: **877-921-7873**

NDC 59088-156-54

Rx Only



30 Capsules

## Supplement Facts

Amount Per Serving	% Daily Value	
Vitamin D3 (as Cholecalciferol)	15 mcg (600 IU)	75%
Vitamin B6 (as Pyridoxine Hydrochloride)	1.5 mg	88%
Folate (as L-5-Methyltetrahydrofolate calcium salt) (1000 mcg as L-5-Methylfolate)	1700 mcg DFE	417%
Calcium (as Calcium Carbonate)	220 mg	17%
Magnesium (as Magnesium Oxide)	100 mg	24%
Rhapontic Rhubarb (Siberian Rhubarb) Root Extract	4 mg	*

**Other Ingredients:** DL-Alpha Tocopheryl Acetate, Magnesium Stearate, Microcrystalline Cellulose, Vegetable Capsule.

**WARNING:** Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Store at controlled room temperature 20° to 25°C (68° to 77°F). [See USP]. Protect from light and moisture and avoid excessive heat.

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**PureTek Corporation**  
Panorama City, CA 91402  
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List No:156541FA Rev: 38490



## MENATROL

folate, multivitamin capsule

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:59088-156
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	1.5 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	600 [iU]
<b>LEVOMEFOLATE CALCIUM</b> (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLATE CALCIUM	1000 ug
<b>MAGNESIUM OXIDE</b> (UNII: 3A3U0G171G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	100 mg
<b>RHUBARB</b> (UNII: G280W4MW6E) (RHUBARB - UNII:G280W4MW6E)	RHUBARB	4 mg
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	220 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	

## Product Characteristics

<b>Color</b>	yellow (Light Yellow)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-156-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/18/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/18/2023	

**Labeler** - PureTek Corporation (785961046)

Revised: 12/2023

PureTek Corporation