INFLAMEX- 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.

Inflamex

DESCRIPTION:

Inflamex[™] is a unique formulation of selected natural ingredients such as Turmeric, Black Pepper, Garlic and Proprietary Extract Blend combined with Niacin and Folate. This potent blend is designed to support your body's response to inflammation and its natural healing processes.

Each capsule contains:

Niacin (as Niacinamide)	25 mg
Folate (as L-5-Methyltetrahydrofolate calcium salt)	1700 mcg DFE
(1000 mcg of L-5-Methylfolate)	
Turmeric Root Extract	100 mg
Garlic Bulb Extract	. 10 mg
Pepper Seed Extract	5 mg
Proprietary Extract Blend	400 mg

Other Ingredients:

Magnesium Stearate, Microcrystalline Cellulose, Oryza Sativa (Rice) Starch, Vegetable Capsule.

Contraindications:

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. **Inflamex™** is contraindicated in patients with gastrointestinal conditions, such as gastric ulcers or gastroesophageal reflux disease (GERD), as they may experience irritation or worsening of symptoms due to the presence of ingredients like garlic and black pepper. Patients with blood clotting disorders or who are on anticoagulant therapy should use caution when consuming high doses of ingredients like garlic, turmeric, and black pepper, as they may have mild blood-thinning effects.

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.

Pregnancy and Lactation:

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

For use on the order of a licensed healthcare practitioner.

If a patient experiences any side effects, call your doctor. 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:

Allergic reactions to any of the ingredients can occur, ranging from mild skin irritation to severe anaphylaxis in rare cases. Allergic sensitization has been reported following both oral and parenteral administration of folate.

Niacinamide, a form of niacin, may cause flushing, itching, and tingling sensations in some individuals, particularly when taken in higher doses. This effect is usually harmless but can be uncomfortable. Some individuals may experience gastrointestinal symptoms such as nausea, bloating, or diarrhea, especially when consuming higher doses of certain ingredients like garlic and black pepper. Certain ingredients in the product, such as garlic and black pepper, may interact with medications. Garlic may potentiate the effects of anticoagulant medications, while black pepper may affect the metabolism of certain drugs.

Dosage and Administration:

One (1) **Inflamex** ™ capsule daily or as directed by a licensed healthcare practitioner. Do not administer to children under the age of 12.

How Supplied:

Inflamex[™] are light orange powder with black specks, in vegan hard shell capsules. One bottle contains 30 capsules (NDC 59088-191-54). 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.

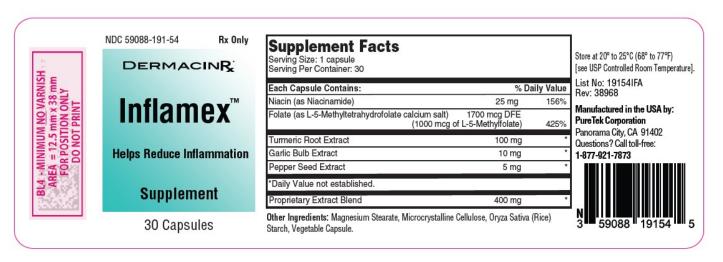
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Inflamex™

Manufactured in the USA by:

PureTek Corporation

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



INFLAMEX

multivitamin capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:59088-191
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BLACK PEPPER (UNII: KM66971LVF) (BLACK PEPPER - UNII: KM66971LVF)	BLACK PEPPER	5 mg
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	25 mg
GARLIC (UNII: V1V998DC17) (GARLIC - UNII:V1V998DC17)	GARLIC	10 mg
TURMERIC (UNII: 856YO1Z64F) (TURMERIC - UNII:856YO1Z64F)	TURMERIC	100 mg
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLATE CALCIUM	1700 ug

Inactive Ingredients	
Ingredient Name	Strength

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
GELLAN GUM (LOW ACYL) (UNII: 7593U09I4D)	
STARCH, RICE (UNII: 4DGK8B7I3S)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics			
Color	orange (Light orange with black specks)	Score	no score
Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	
Contains			

l	Packaging				
	# Item	Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:590		30 in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2024	

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
	06/12/2024		
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date	

Labeler - PureTek Corporation (785961046)

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