

**VARVIMAX™ - Choline L -Bitartrate, Curcumin 95%, Trans - Resveratrol 98% (Polygonum cuspidatum Extract (root)), 5 -HTP (from Griffonia Seed Extract) 99%, L - Glutamine, L -Arginine HCl, L -Serine, Astaxanthin, Black Pepper Extract 95%, Gamma -Aminobutyric Acid (GABA), Boswellia Extract (Boswellia serrata)65% Boswellic Acid, Docosahexaenoic acid (DHA)/ Eicosapentaenoic acid (EPA), Matcha Green Tea Leaf Powder, Panax Ginseng Root Powder.**

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## **VARVIMAX™ Capsules**

### **DESCRIPTION**

VARVIMAX™ is a medical food for the clinical dietary management of chronic pain, fatigue, and inflammatory conditions. It has been specifically designed by medical practitioners and scientists to help to restore and maintain the balance of neurotransmitters in your body. Dispense by prescription. Use under medical supervision.

### **VARVIMAX™ Capsule 748mg**

Each vegetarian capsule contains a proprietary composition of 748mg of 5-HTP, Choline L-Bitartrate, Gamma-Aminobutyric Acid (GABA), L-Arginine HCl, L-Glutamine, L-Serine, Astaxanthin, Piperine (Black Pepper Extract 95%), Boswellia Extract (Boswellia serrata) 65% Boswellic Acid, Curcumin 95%, Docosahexaenoic acid (DHA), Eicosapentaenoic acid (EPA), Trans-Resveratrol 98% (Polygonum cuspidatum Extract (root)), Matcha Green Tea Powder, Panax Ginseng Root Powder and Vitamin B6 (Pyridoxine HCl).

### **Dietary Ingredients**

Choline L -Bitartrate, Curcumin 95%, Trans - Resveratrol 98% (Polygonum cuspidatum Extract (root)), 5 - HTP (from Griffonia Seed Extract) 99%, L - Glutamine, L -Arginine HCl, L -Serine, Astaxanthin, Black Pepper Extract 95%, Gamma -Aminobutyric Acid (GABA), Boswellia Extract (Boswellia serrata)65% Boswellic Acid, Docosahexaenoic acid (DHA)/ Eicosapentaenoic acid (EPA), Matcha Green Tea Leaf Powder, Panax Ginseng Root Powder.

### **Indications and Usage**

VARVIMAX™ is indicated for the dietary management of the metabolic disorders involved in chronic pain, inflammatory conditions, and fatigue.

### **Intended Use**

Medical foods are intended for the patient who has a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone.

VARVIMAX™ offers a unique composition of compounds, including essential amino acids and flavonoids, which are not typically obtained through regular diet. These components provide distinct benefits for individuals seeking to address chronic pain, fatigue, or inflammatory conditions. Flavonoids, found naturally in various sources such as fruits, vegetables, cocoa, red wine, and green tea, possess remarkable anti-

inflammatory properties. These organic molecules have the capacity to reduce inflammation within the body, contributing to improved overall wellbeing(1). Meanwhile, essential amino acids like arginine and tryptophan play a significant role in neurotransmission, facilitating the transmission of information between cells(2). As essential building blocks for neurotransmitters, these amino acids have a vital function in regulating pain and inflammation in the body. Individuals experiencing chronic pain, fatigue, or inflammatory conditions may be deficient in these essential amino acids. By addressing these deficiencies through supplementation with VARVIMAX™, individuals have the potential to restore balance and support their body's natural mechanisms for pain regulation, inflammation control, and overall health.

VARVIMAX™ is a dietary supplement, harnessing the power of essential amino acids and flavonoids to offer a solution for those seeking relief from chronic pain, fatigue, or inflammatory conditions.

VARVIMAX™ Capsules should always be used under medical supervision.

## **Background**

Chronic inflammatory conditions can cause significant pain and discomfort in affected individuals. Current treatments, such as nonsteroidal anti-inflammatory drugs (NSAIDs), are associated with adverse effects and do not always provide adequate relief. Therefore, there is a need for safe and effective treatments for chronic inflammation and pain in arthritis and fibromyalgia.

VARVIMAX™, a medical food which addresses the dietary deficiencies in patients with inflammatory conditions, contains a combination of herbs and natural ingredients believed to have anti-inflammatory and analgesic properties. The natural ingredients in VARVIMAX™, such as Astaxanthin, Curcumin, Panasang Ginyang, and Matcha green tea powder have been traditionally used in different parts of the world for their medicinal properties, and scientific studies have demonstrated their anti-inflammatory and analgesic effects. Earlier research has shown that Astaxanthin can decrease the expression of MMP induced by IL-1 $\beta$  in chondrocytes and improve cartilage loss in osteoarthritis experiments(3).

## **Different Ingredients found in VARVIMAX™**

### **5-HTP**

5-HTP, or L-5-hydroxytryptophan, is found in both medications and dietary supplements. It is derived from tryptophan through the action of tryptophan hydroxylase. 5-HTP plays a significant role in the development of neurological and metabolic disorders, and its conversion from tryptophan is the crucial step in the production of serotonin and melatonin(4).

### **Choline L- Bitartrate**

Choline L-Bitartrate is an amino acid known for its role in synthesizing acetylcholine, which acts as an anti-nociceptive agent. While no direct studies have specifically examined the effects of Choline L-Bitartrate on reducing symptoms of fibromyalgia and arthritis, research has indicated its effectiveness in alleviating pain and inflammation in various inflammatory conditions. One notable finding is that choline has a selective agonistic effect on alpha 7-type nicotinic acetylcholine receptors found in both neuronal and non-neuronal cells involved in pain signal transmission. This interaction triggers a series of reactions that result in anti-inflammatory effects. In the context of postoperative patients, a study demonstrated that choline supplementation reduced symptoms of inflammatory hyperalgesia(5).

## **GABA**

GABA, an inhibitory neurotransmitter found in the central nervous system, plays a vital role in reducing the excessive activity of nerve cells. Through its ability to regulate nerve cell activity, GABA has the potential to provide symptom relief and improve the management of arthritis and fibromyalgia. Research suggests that GABA can reduce the transmission of pain signals to the brain in cases of arthritis(6,7).

## **L-Arginine**

L-Arginine, an amino acid, plays a crucial role in the synthesis of Nitric oxide, a molecule involved in immune system regulation and blood vessel dilation. Numerous studies have demonstrated that L-Arginine supplementation leads to notable improvements in disease activity and a reduction in inflammatory markers in the bloodstream. In one study, researchers investigated the impact of L-Arginine supplementation in mouse models of arthritis, as well as its metabolic effects during the differentiation of osteoclasts in the presence of inflammation(8).

## **L-Glutamine**

L-glutamine is an amino acid that occurs naturally in the body and is classified as a non-essential amino acid. It plays a crucial role in the body's metabolism. In certain situations, L-glutamine may be utilized as a medical food supplement to assist in pain reduction. Besides its analgesic properties, it also contributes to strengthening the immune system, facilitating tissue regeneration, and improving the absorption of nutrients. Furthermore, L-glutamine is involved in the synthesis of neurotransmitters, which can influence the pathways related to the perception of pain(9).

## **L-Serine**

L-serine has demonstrated potential in the treatment of various neurological conditions such as epilepsy, schizophrenia, psychosis, and Alzheimer's Disease, among others. Additionally, animal studies involving L-serine administration and human clinical trials exploring its therapeutic effects generally indicate its safety profile(10).

## **Astaxanthin**

Astaxanthin has garnered attention for its potential to alleviate pain and reduce inflammation within the body. Researchers have explored several hypotheses regarding the specific mechanisms through which astaxanthin exerts its pain-reducing effects(11). One study suggests that astaxanthin diminishes inflammation and oxidative stress, both of which play a role in the development and exacerbation of chronic pain conditions such as arthritis and neuropathic pain(12) by acting as an antioxidant and anti-inflammatory agent, astaxanthin may help reduce oxidative stress and inflammation, leading to a potential alleviation of pain.

## **Black Pepper (Piperine)**

Black pepper, known as the "king of spices," is widely utilized for culinary purposes and holds medicinal significance in various cultures(13). Scientific research has uncovered that piperine, the compound responsible for the pungency of black pepper and long pepper, possesses stimulatory properties on the entire gastrointestinal tract, as well as the liver and pancreas. It stimulates the salivary glands, leading to increased saliva production and activation of salivary amylase. Furthermore, in the stomach, piperine promotes the secretion of gastric juices and activates histamine H2 receptors(14). Black Pepper also enhances the absorption of various supplements, like Curcumin.

## **Boswellia Extract**

Boswellia Extract (*Boswellia serrata*) 65% Boswellic Acid has been shown to have the following benefits in chronic inflammation and pain<sup>123</sup>:

Helps to control the arthritis that occurs when flexible tissue at the ends of bones wears down

Helps to reduce the chronic inflammatory disorder affecting many joints, including those in the hands and feet

Reduces the inflammation of the fluid-filled pads (bursae) that act as cushions at the joints

Suppresses joint inflammation and pain by targeting key enzymes that facilitate the release of pro-inflammatory chemicals in the joints<sup>2</sup>

Reduces chronic inflammation in patients with ulcerative colitis<sup>3</sup>

## **Curcumin 95%**

Curcumin is a compound that is found in turmeric. It is the active substance in Turmeric. It has been famous for its use as an antioxidant and anti-inflammatory agent. Curcumin reduces arthritis symptoms in multiple ways. Curcumin, a polyphenol compound, exhibits a multifaceted approach in targeting various signaling molecules and exerting beneficial effects at the cellular level<sup>(15)</sup>. Its wide range of health benefits includes supporting inflammatory conditions<sup>(16)</sup>, metabolic syndrome <sup>(17)</sup>, pain management<sup>(18)</sup>, as well as aiding in the management of inflammatory and degenerative eye conditions <sup>(19,20)</sup>. While curcumin supplementation offers numerous therapeutic advantages, the primary mechanisms behind these benefits are largely attributed to its antioxidant and anti-inflammatory properties<sup>(21)</sup>.

## **Docosahexaenoic Acid (DHA)**

Docosahexaenoic Acid (DHA) is an “omega-3 fatty acid” that can reduce the severity of Arthritis symptoms in rats with “collagen-induced arthritis”. That’s because it has anti-inflammatory effects that help to reduce joint damage and inflammation, it also improves cell function and enhance metabolism<sup>(22,23)</sup>.

## **Eicosapentaenoic Acid (EPA)**

Eicosapentaenoic acid (EPA) is an omega-3 fatty acid commonly found in oily fish such as salmon and mackerel. It has demonstrated anti-inflammatory effects, which can be beneficial in the management of arthritis. Omega-3 fatty acid including EPA, reduced pain and stiffness in individuals with Osteoarthritis (OA)<sup>(22,23)</sup>.

## **Trans-Resveratrol 98% (polygonum cuspidatum extract)**

Resveratrol, a natural antioxidant polyphenol, has gained significant attention in recent years and is found in red wines, grapes, and the roots of *polygonum cuspidatum*<sup>(24,25)</sup>. This potent polyphenolic compound possesses various biological functions, including anti-inflammatory and antioxidant properties. Resveratrol has been found to exhibit health-enhancing properties such as protection against cardiovascular disease and inhibition of cancer, as supported by scientific research<sup>(26,27)</sup>.

## **Matcha Green Tea Powder**

Green tea offers various health benefits due to its natural antioxidants<sup>(28)</sup>. These antioxidants, known as polyphenols, make up a significant portion, approximately 30%, of the dry weight of green tea<sup>(29)</sup>. Polyphenols are highly potent antioxidants, comparable to vitamins C and E, carotene, and tocopherol in terms of their effects<sup>(30,31)</sup>.

## **Panax Ginseng Root Powder**

Ginsenosides, found in Panax Ginseng, exhibit a wide range of therapeutic benefits, such as antioxidant properties, anti-inflammatory effects, vasorelaxation, anti-allergic actions, antidiabetic effects, and anticancer activity. Currently, around 40 distinct ginsenoside compounds have been documented(32).

## **Vitamin B6**

Vitamin B6 has been observed to enhance the resilience of the nervous system in individuals experiencing chronic pain, resulting in pain reduction. Research studies have indicated that vitamin B6 can partially alleviate thalamic-evoked nociceptive burst discharge and provide relief from mechanical allodynia in diabetic rats(33).

**VARVIMAX™** is formulated with a carefully balanced blend of ingredients that are specifically combined to address the dietary management of metabolic disorders associated with chronic pain, inflammatory conditions, and fatigue.

## **CONTRAINDICATIONS**

**VARVIMAX™** is contraindicated in patients with known to hypersensitivity to any of the ingredients mentioned in the product.

Do not use if pregnant.

**VARVIMAX™** ingredient (Docosahexaenoic acid (DHA)/Eicosapentaenoic acid (EPA))(34) is contraindicated for patients suffering from severe chronic pain or chest pain while resting.

It is not applicable for the patients suffering from unstable angina(35).

## **PRECAUTIONS**

**Talk to the doctor before taking VARVIMAX™.**

- If you previously had stomach or intestines ulcer or bleeding, it is advised not to take **VARVIMAX™** without doctor prescription.
- In the case of dehydration, severe sickness or diarrhea, **VARVIMAX™** is not recommended.
- If you suffer from serious allergic reaction to any vegetarian ingredient such as 5-HTP (Griffonia Seed Extract), Black Pepper Extract, Panax Ginseng Root Powder or Matcha Green Tea Leaf Powder or suffer from skin reaction to any of the ingredient, the **VARVIMAX™** capsules are not recommended.
- If you feel sick, fever, or infection or feel any symptoms of infection or severe inflammation, the **VARVIMAX™** is not advised(36).
- The consumption of alcohol may increase the hypersensitivity to the **VARVIMAX™** medicine.
- **VARVIMAX™** is not recommended for under 18 years old.

## **INTERACTIONS WITH DRUGS**

While we can provide information on potential interactions for substances used in **VARVIMAX™**, it is important to note that the interactions between multiple drugs and herbal extracts can be complex and vary depending on individual factors. The individual responses to drug interactions can vary. Additionally, the available evidence on specific interactions for these combinations is limited. It's crucial to consult with a

healthcare professional before combining multiple drugs or herbal extracts. Here is some information of interaction with other drugs.

### *Anti-depressant medicines*

Selective Serotonin Reuptake Inhibitors (SSRIs) are a class of antidepressant medications that work by increasing serotonin levels in the brain. Combining 5-HTP (Constituent of VARVIMAX™) with SSRIs may increase the risk of serotonin syndrome, a potentially serious condition characterized by symptoms such as agitation, rapid heartbeat, confusion, and high body temperature. It is generally recommended to avoid combining 5-HTP with SSRIs due to this risk(37,38).

Panax ginseng, found in VARVIMAX™ capsules, may decrease the effectiveness of warfarin (Coumadin). When Panax ginseng is used together with the monoamine oxidase inhibitor phenelzine (Nardil), it could result in manic-like symptoms(39,40).

### *Anticoagulant / Antiplatelet Drugs*

Astaxanthin and Curcumin 95% both have mild anticoagulant properties, which means it can potentially enhance the effects of drugs that also have anticoagulant or antiplatelet properties, such as aspirin, warfarin, clopidogrel, and heparin. This could increase the risk of bleeding, so individuals should exercise caution when using astaxanthin or Curcumin 95% or consider adjusting their dosage. Therefore, it is important to be aware of the potential risk of bleeding complications when administering astaxanthin concurrently with warfarin(41).

### *Warfarin/ Coumadin*

Warfarin along with VARVIMAX™ may slow down the blood clotting process and can increase the risk of bleeding(42).

### *Multi-Vitamins*

Many multivitamins contain valproic acid, phenytoin, or carbamazepine that increases the rate of Vitamins. This will result in low PLP rate and hyper-homo-cysteinemia(43) This will increase the risk of vascular events or epileptic seizures like reduces the control seizures in patients or stroke. There are many patients with the history of taking multi-vitamins for several years this will increase the chances of chronic vascular toxicity.

## **Dosage and Administration**

The recommended dose is up to four (4) capsules of VARVIMAX™ daily, with or without meals. VARVIMAX™ can be taken all at once, or two (2) capsules in the morning and two (2) capsules in the afternoon. If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not double your next dose or take more VARVIMAX™ than prescribed. Capsules should be swallowed whole and not crushed or chewed. As any medication, we strongly recommend taking VARVIMAX™ under medical supervision.

## **How Supplied**

VARVIMAX™ is supplied in clear vegetarian capsules in bottles of 120 capsules. NDC 86000-37246-37

## **Storage**

Keep tightly closed in a cool dry place 45°F to 90°F (08°C to 32°C). Protect from light and moisture. VARVIMAX™ is supplied in a recyclable plastic bottle with a child-resistant cap. Varvimax™ is available as

a transparent oval vegetarian capsule, with pale yellowish powder content. Commercial product is supplied in bottles of one hundred twenty (120) capsules, a 30-day supply.

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Fort Lauderdale, FL 33308  
Made in USA

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

**LANFAM**

86000-37246-37

**VARVIMAX™**

Medical Food, 120 capsules

### Description:

Each clear vegetarian VARVIMAX™ with each capsule containing 748mg of:



5-HTP
Choline L-Bitartrate
Gamma-Aminobutyric Acid (GABA)
L-Arginine HCl
L-Glutamine
L-Serine
Astaxanthin
Piperine - Black Pepper Extract 95%
Boswellia Extract (Boswellia serrata) 65% Boswellic Acid
Curcumin 95%
Docosahexaenoic acid (DHA)
Eicosapentaenoic acid (EPA)
Trans-Resveratrol 98% (Polygonum cuspidatum Extract (root))
Matcha Green Tea Powder
Panax Ginseng Root Powder
Vitamin B6 (Pyridoxine HCl)

## **DOSAGE AND ADMINISTRATION**

The recommended dose is four capsules daily. VARVIMAX™ can be taken all at once, or two (2) capsules in the morning and two (2) capsules in the afternoon or as directed by a licensed medical practitioner.

## **STORAGE**

Store in a controlled room of 45°F to 90°F (08°C to 32°C).

## **Ingredients:**

Choline L -Bitartrate, Curcumin 95%, Trans - Resveratrol 98% (Polygonum cuspidatum Extract (root)), 5 - HTP (from Griffonia Seed Extract) 99%, L - Glutamine, L -Arginine HCl, L -Serine, Astaxanthin, Black Pepper Extract 95%, Gamma -Aminobutyric Acid (GABA), Boswellia Extract (Boswellia serrata)65% Boswellic Acid, Docosahexaenoic acid (DHA)/ Eicosapentaenoic acid (EPA), Matcha Green Tea Leaf Powder, Panax Ginseng Root Powder.

## **USE**

VARVIMAX™ This medical food is dispensed by prescription for dietary management of chronic pain, fatigue, and inflammatory conditions. It has been specifically designed by medical practitioners and scientists to help to restore and maintain the balance of neurotransmitters in your body.

Use under medical supervision.

Dispense in a tight, light-resistant container.

KEEP OUT OF REACH OF CHILDREN.

**DIRECTIONS FOR USE:**

**FOR ADULTS ONLY:** As a Medical Food, take up to 4 capsules daily, or as directed by your physician. VarviMax™ can be taken with or without food.

**NOTICE:** THIS PRODUCT IS TO BE USED UNDER THE DIRECT SUPERVISION OF A PHYSICIAN OR OTHER LICENSED HEALTHCARE PRACTITIONER.

For the dietary management of chronic pain, inflammatory disorders, and fatigue.

**STORAGE:** Keep tightly closed in a cool dry area 45°-90 °F (8-32 °C).

**WARNING:** Keep this product out of the reach of children. Consult your physician prior to using this product if you are pregnant, nursing, taking medication, or have a medical condition. Discontinue use two weeks prior to surgery. Keep out of reach of children.

CONTAINS NO ARTIFICIAL COLORS OR FLAVORS. NO WHEAT, NO GLUTEN, NO SOY, NO DAIRY, YEAST FREE



**VARVIMAX™**

86000-37246-37

MEDICAL FOOD  
FOR THE DIETARY MANAGEMENT OF:  
PAIN DISORDERS  
INFLAMMATORY CONDITIONS  
AND FATIGUE

120 CAPSULES  
748 MG / CAPSULE

**Supplement Facts**

Serving Size: 4 Capsules (2994mg)  
Servings Per Container: 30

Amount Per Serving	% DV
Vitamin B6 (as Pyridoxine HCl) 1.7mg	100%*
<b>Proprietary Blend</b> 2994mg	†
Choline L-Bitartrate, Curcumin 95%, Trans-Resveratrol 98% (Polygonum cuspidatum Extract (root)), 5-HTP (from Griffonia Seed Extract) 99%, L-Glutamine, L-Arginine HCl, L-Serine, Astaxanthin, Black Pepper Extract 95%, Gamma-Aminobutyric Acid (GABA), Boswellia Extract (Boswellia serrata) 65% Boswellic Acid, Docosahexaenoic acid (DHA), Eicosapentaenoic acid (EPA), Matcha Green Tea Leaf Powder, Panax Ginseng Root Powder	

\*Percent Daily Values (DV) are based on a 2,000-calorie diet.

†Daily Value (DV) not established.

**Other Ingredients:** Dicalcium Phosphate, Microcrystalline Cellulose, Stearic Acid, Croscarmellose Sodium, Silicon Dioxide, Magnesium Stearate.

MANUFACTURED FOR:  
LANFAM LLC  
Fort Lauderdale, FL 33308



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**VARVIMAX™**

Clear Vegetarian Capsules

**Product Information**

<b>Product Type</b>	MEDICAL FOOD	<b>Item Code (Source)</b>	86000-37246-37
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
5 -HTP (from Griffonia Seed Extract) 99%	AMINO ACID	
CHOLINE L- BITARTRATE	AMINO ACID	
GAMMA – AMINOBUTRYIC ACID (GABA)	AMINO ACID	
L -ARGININE HCl	AMINO ACID	
L - GLUTAMINE	AMINO ACID	
L-SERINE	AMINO ACID	
ASTAXANTHIN	SUPPLEMENT	
BLACK PEPPER EXTRACT 95%	SUPPLEMENT	
BOSWELLIA EXTRACT (Boswellia Serrata)65% Boswellic Acid	SUPPLEMENT	
CURRUMIN 95%	SUPPLEMENT	
DOCOSAHEXAENOIC ACID (DHA)	SUPPLEMENT	
EICOSAPENTAENOIC ACID (EPA)	SUPPLEMENT	
TRANS-RESERATROL 98% (Polygonum cuspidatum Extract (root))	SUPPLEMENT	
MATACHA GREEN TEA POWDER	SUPPLEMENT	
PANAX GINSENG ROOT POWDER	SUPPLEMENT	
VITAMIN B6 (Pyridoxine HCl)	VITAMIN	

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
MISROCRYSTALLINE CELLULOSE	
STEARIC ACID	
DICALCIUM PHOSPHATE	
CROSCARMELLOSE SODIUM	
MAGNESIUM STEARATE	
SILICON DIOXIDE	
PHARMACEUTIC GLAZE	

### Product Characteristics

<b>Color</b>	PALE YELLOWISH	<b>Score</b>	no score
<b>Shape</b>	VEGERTARIAN	<b>Size</b>	00
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	86000-37246-37	120 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
MEDICAL FOOD			

**Labeler - LANFAM LLC**

Revised: 5/2023

Lanfam LLC