

PALMITIC ACID
MONO ETHANOLAMIDE
CAPSULES 300 mg
PALMIFLAM



Physical Description: White colored powder filled in off white color size "0"veg capsule.

Strength: 300 mg/serving

Dosage form: Solid dosage form -Capsules

Product composition: Each capsule contains, Palmitic acid mono ethanolamide (PEA) 300 mg Excipients q.s.

Nutritional Information:

(Nutritional Information (Approx.))	Per 100 g	Per Serve	% RDA Per serve
Energy (Kcal)*	322.25	1.29	0.06
Protein (g)	22.50	0.09	0.20
Carbohydrate (g)	57.50	0.23	#
Total sugars (g)	0.00	0.00	#
Added sugars (g)*	0.00	0.00	0.00
Total Fat (g)*	0.25	0.001	0.001
Sodium (mg)*	189.50	0.76	0.04
Palmitic acid mono ethanolamine	300 mg	#	

*%RDA calculated as per ICMR 2020 for sedentary work women.
#%RDA calculated as per 2000Kcal diet for an average adults.

#%RDA not established.

Ingredients: Palmitic acid mono ethanolamide, Hydroxy Propyl Methyl Cellulose Capsule (INS 464), Diluent (INS170 (i)), Maltodextrin (Diluent), Stabilizer (INS 1202), Glazing Agent (553(iii)), Stabilizers (INS 407) and (INS 261)), Anti-caking agent (INS 551) and Colour (INS 171).

Food Category: FOOD FOR SPECIAL MEDICAL PURPOSE (FSMP)

RECOMMENDED TO BE USED UNDER MEDICAL ADVICE ONLY

For the dietary management of Joint health and chronic pain management of different etiologies.

Mode of Action: PEA used as analgesic and anti-inflammatory properties.

Several preclinical in vitro and in vivo studies have proven that PEA can induce its biological effects by acting on several molecular targets in both central nervous systems (CNS) and peripheral nervous systems (PNS). PEA has quite unique anti-inflammatory property over other classic anti-inflammatory drugs due to its bipolar (Both CNS &

PNS) mechanisms of action. The preclinical studies indicate that PEA, especially in micronized or ultra-micronized forms (i.e., formulations that maximize PEA bioavailability and efficacy), could be a potential therapeutic agent for the effective treatment of different pathologies characterized by neuro-degeneration, inflammation, and pain. In particular, the potential neuro-protective effects of PEA have been demonstrated in several experimental models of Alzheimer's disease. PEA utilizes the endocannabinoid system, potentiating its actions at CB1, CB2, and GPR55 receptors, and TRPV1 channels for supporting joint function, reducing joint stiffness and providing joint comfort. PEA reduces production of inflammatory mediators such as TNF Alpha and effects on Neurotrophic Factors like NGF.

Pharmacokinetic Data:

ADME: PEA is a highly lipophilic compound that raises issues concerning its formulation for optimal absorption. Time taken to reach tissue level 50-180 min (the maximum time point) after administration. In addition to its absorption, the presystemic metabolism of PEA is an important determinant of its bioavailability. The hydrolytic enzymes involved in PEA metabolism are expressed in the intestine and the liver. As with the absorption and presystemic metabolism of PEA, data on the distribution of PEA are few and far between, and in most cases, they are confined to measures of blood levels of the compound after oral administration. Following a dose of 300 mg of micronized PEA to humans, an approximate doubling of levels of the lipid were seen in plasma two hours after administration, falling back to normal levels by 4 and 6 h. In the rat, approximately 1% of the oral dose of PEA was recovered in the brain, particularly in the hypothalamus, with notable accumulation also in the pituitary and adrenal glands. PEA is enzymatically hydrolysed to form palmitic acid and ethanolamine. Orally or topically administered PEA is hydrolysed to palmitic acid prior to its excretion from the body through kidney.

Toxicological Information: LD₅₀ was > 5 g/kg. Safe dose estimate > 500 mg/kg/day in Rats & Mice and 100 mg/kg/day in Dogs. No teratogenic or embryo toxic effects in study on pregnant and new born mice. No side effects were observed in new born mice.

Product safety data: Product is safe as per recommended daily dose.

Instruction for use: Should be administered orally with a fat containing meal or snack.

Recommended usage level: One capsule per day. Not to exceed the recommended daily usage.

The product is not for parenteral use.

This product is not intended to diagnose, treat, cure or prevent any disease.

Side Effects: PEA is that it is a naturally occurring agent produced by the body that has no reported serious side effects or drug-drug interactions, making it a better treatment option for pain management. Few patients who are sensitive to PEA may show mild side effects like upset stomach.

Drug-Drug Interaction: PEA is that it is a naturally occurring agent produced by the body that has no reported serious side effects or drug-drug interactions. It does not interfere with other medication therapies nor does it trigger drug-drug interactions.

Incompatibility: Incompatible with strong oxidizing agents and products with Opioid derivatives.

Pregnancy and breast-feeding: There isn't enough reliable information to know if PEA is safe to use when pregnant or breast feeding. It is good to avoid use during Pregnancy or breast feeding.

Infants and children: There isn't enough reliable information to know if PEA is safe in infants and children. It is good to avoid use of PEA in infants and children.

Veg/Non Veg Declaration: Product is Vegetarian product.

GMO/Non-GMO Declaration: Product is GMO free.

Allergen Information: Manufactured in a facility that processes Milk and soy ingredients.

Organic Solvent Declaration: Free from Class I & Class II solvents.

Storage condition: Store at a temperature not exceeding 25°C. Protect from light & moisture. Product is required to be stored out of reach of children.

Pack Profile: 10 Capsules packed in Alu/ Alu blister packed in printed carton with PIL.

Shelf life: 18 Months from date of manufacturing.

Manufactured by:
Tirupati Lifesciences Private Limited.
Nahan Road, Paonta Sahib,
Distt. Simaur (HP) – 173025, India

Lic No.: 10012062000165

Marketed by:

INTAS


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079 61577493
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TLPEAPIL02

Front Side

Back Side

Generic Name: 11 - Helvetica-Light

Brand Name: 9 - Helvetica-Black

	AW No./AW Code :		TLPEAPIL02	
	Size :		80 x 110 (mm)	
Pantone No. :	347 C & Black			
Date :	25/11/22			
Checked by :	Packaging Dev.	Packaging Dev.	C.Q.A.	Approved by C.Q.A.
Signature & Date				