

# PALMITOLE

Breakthrough Approach | Novel Solution | Patent Applied



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## BACKGROUND:

- Diabetic peripheral neuropathy (DPN) is common with prevalence ranging from 40% to 50% of all patients with longstanding diabetes and is one of the predominant complications with high morbidity, mortality, and amputation risks. There is a lack of treatment options targeting the Diabetic neuropathic pain and its management also remains a challenge.
- **PALMITOLE**, a patent applied product for management of Diabetic neuropathic pain, is a composition of Palmitoylethanolamide, Daidzein & Genistein.

## HOW PALMITOLE WORK?

**PALMITOLE** has an interesting mode of action, it activates a nuclear receptor, the Peroxisome Proliferator-Activated Receptor alpha (PPAR-alpha), which is a master-switch for a great number of genes activating inflammatory cascades.

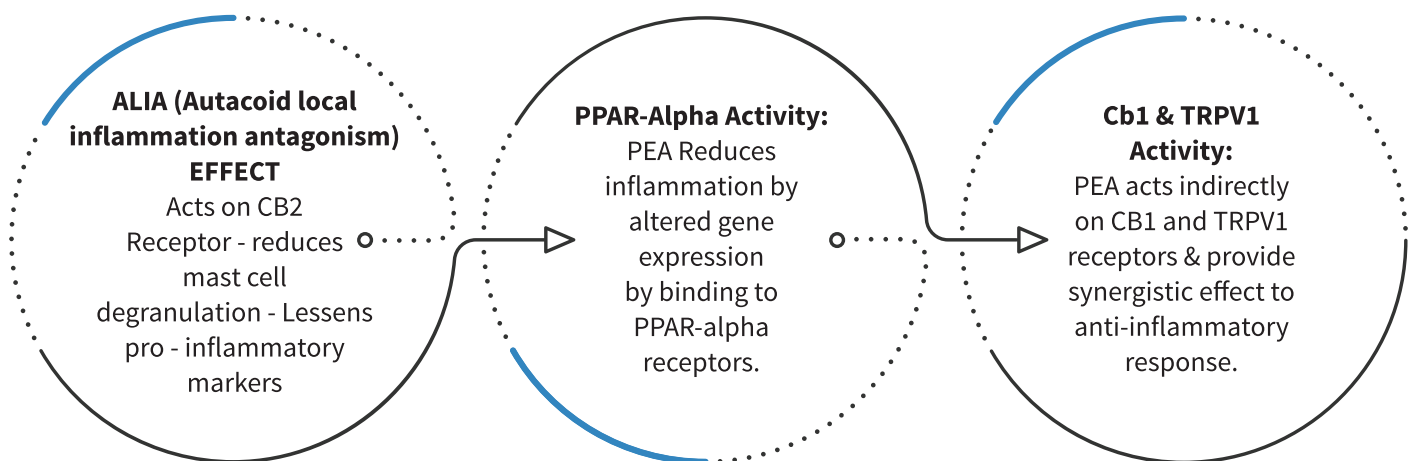
The active components of **PALMITOLE** are:

**PEA (Palmitoylethanolamide):** A Fatty Acid Amide found in human body that restores balance to excessive inflammation.

**Daidzein & Genistein:** Naturally occurring established Fatty Acid Amide Hydrolase (FAAH) Inhibitor to counteract the effect of the FAAH Enzyme.

**MPFAITECH:** Micronized PEA FAAH Inhibitor Manufacturing Technology brought in India by technical collaboration with Enavant Research USA, to help proper distribution and absorption of the formulation at the site of inflammation.

## MECHANISM OF ACTION:



PEA does not operate through just one main mechanism of action. Instead, synergistic interactions among several mechanisms often seem necessary so that PEA can produce its important therapeutic effects, both in the central and the peripheral nervous system.

# CLINICAL STUDY

## OBJECTIVE:

- To evaluate the effectiveness of micronized Palmitoylethanolamide (PEA-m) treatment in reducing the painful symptoms experienced by diabetic patients with peripheral neuropathy.

## METHOD:

- 30 patients, (15M & 15F), between the ages of 53 and 86 affected by Type II diabetes and complaining of neuropathic painful symptoms were enrolled in the study
- 300 mg PEA-m 2 tablets daily for 60 days.
- Patient medical histories revealed the presence of the following comorbidities: hypertension, 46%; cardiopathies, 10%; and chronic obstructive pulmonary disease, Parkinson's disease, and multiple sclerosis, 3%.

## RESULT:

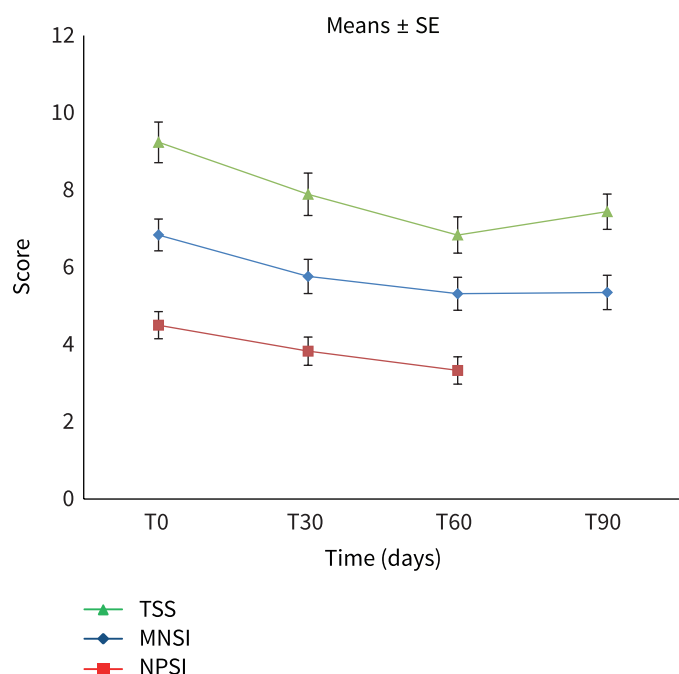


Figure 1: Effect of micronized PEA on diabetic painful neuropathy evaluated by Michigan Neuropathy Screening Instrument (MNSI), Total Symptom Score (TSS), and Neuropathic Pain Symptoms Inventory(NPSI).

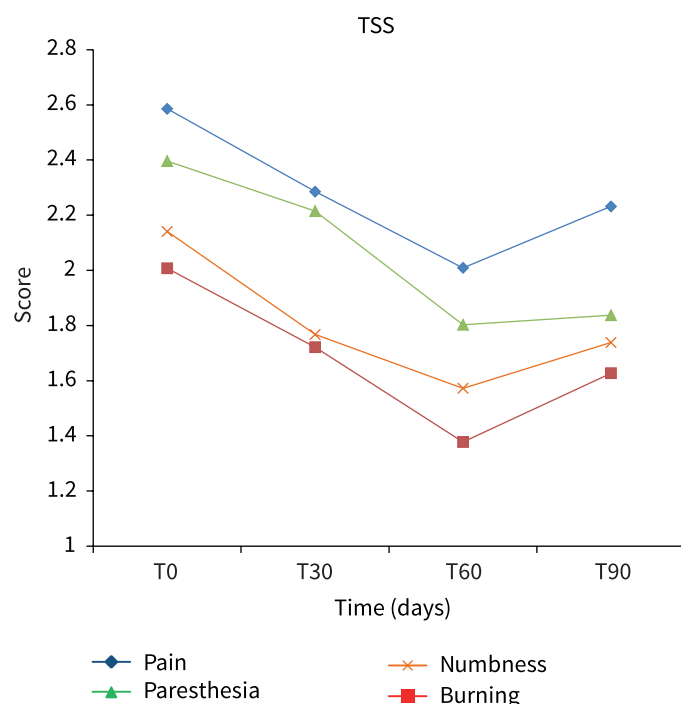


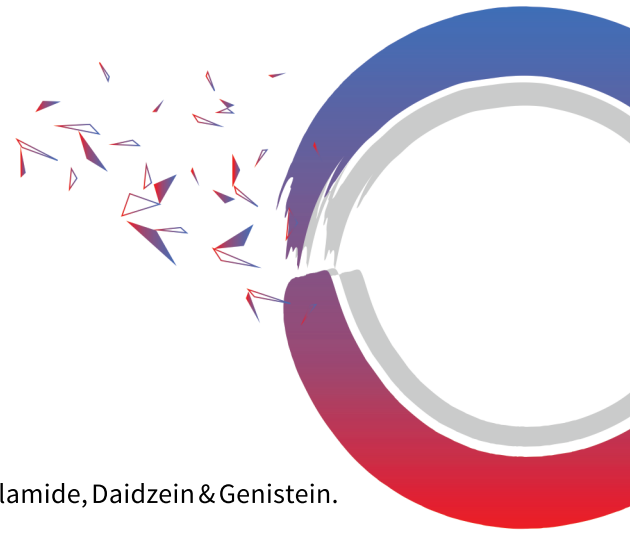
Figure 2: Effect of micronized PEA on each single neuropathic pain symptom assessed by Total Symptom Score (TSS).

## CONCLUSION:

- The findings presented in the current study demonstrate that PEA-m treatment resulted in a significant reduction in the pain symptoms characteristic of diabetic neuropathy after 30 days.
- The median values obtained from MNSI, TSS, and NPSI diminished, compared to baseline, at various observation points until the end of treatment 60 days later, with no adverse side effects.

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## DESCRIPTION:

**PALMITOLE** is a patent applied product. It is a composition of Palmitoylethanolamide, Daidzein & Genistein.

## INDICATION:

**PALMITOLE** is indicated for management of Diabetic peripheral neuropathy.

## COMPOSITION: PALMITOLE

Each serving of vegetarian capsule contains:

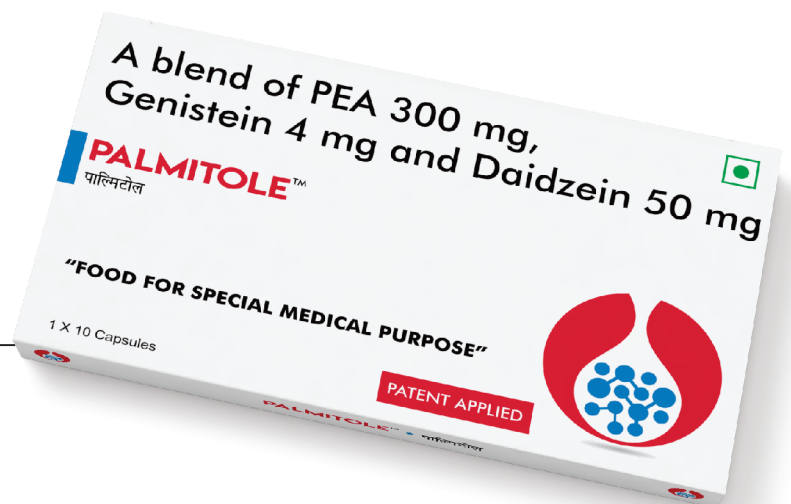
- Palmitoylethanolamide 300 mg
- Daidzein 50 mg
- Genistein 4 mg

## DOSAGE:

One Capsule twice a day or under medical advice of physician.

## MERITS OF PALMITOLE:

- No side effect
- No drug drug interactions
- No adverse drug reactions
- Synergistic effect
- Improves patient's quality of Life



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