

Leash the  
*Triggers*

# PALMIRESP

Palmitoylethanolamide 300 mg, Boswellia Serrata Extract 300 mg  
and Pine Bark Extract 200 mg Tablets





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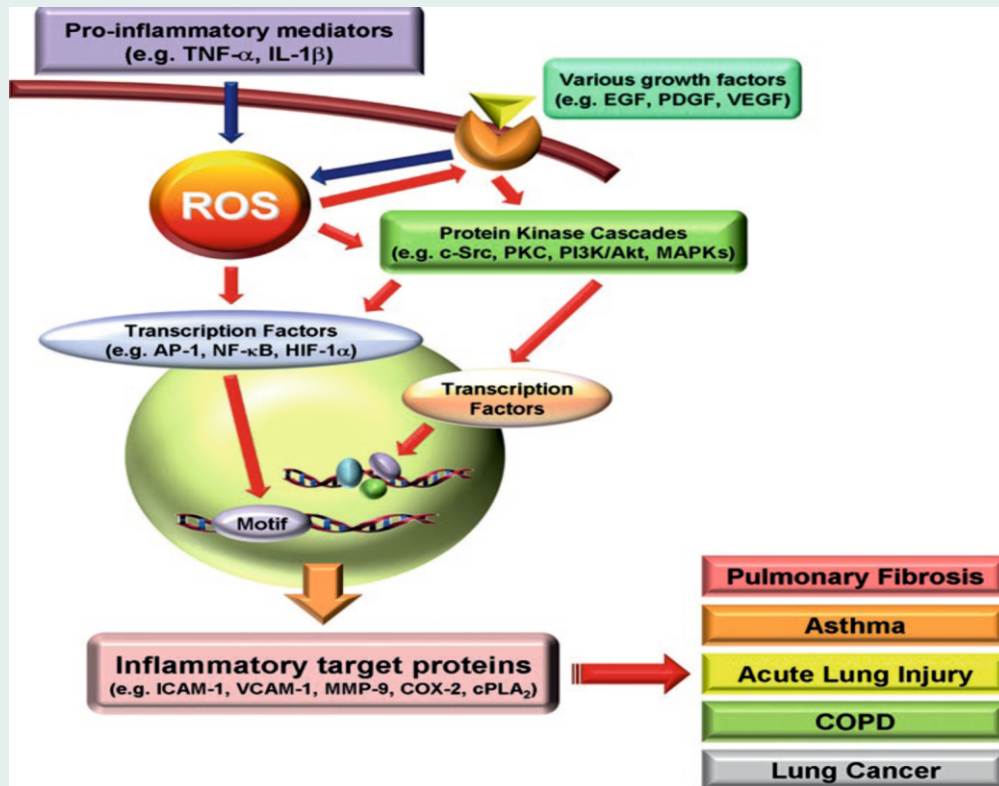
with,

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## AIRWAY INFLAMMATION: HALLMARK OF THE PATHOGENESIS OF RESPIRATORY DISEASES

Chronic airway inflammation is a general feature of some types of asthma, cystic fibrosis (CF), bronchopulmonary dysplasia (BPD), and chronic obstructive pulmonary disease (COPD).



## INFLAMMATORY AND OXIDATIVE DAMAGE:

The inflammation-induced overproduction of reactive oxygen species (ROS) means that endogenous antioxidants may not be sufficient to prevent oxidative damage, and aggravate the inflammatory response. However, given the lack of definite and safe therapies, complementary or alternative medicines are frequently used by asthmatic patients in combination with standard treatments.<sup>1</sup>

## PALMITOYLETHANOLAMIDE: A NATURAL BODY-OWN ANTI-INFLAMMATORY AGENT

- PEA was already identified in the 50s of the last century as a therapeutic substance with potent anti-inflammatory properties.
- In the beginning of the 70s, the modifying effects of PEA on immunological reactions were well established. It has been shown that N-(2-hydroxyethyl)-palmitamide (PEA) can decrease the intensity of several inflammatory and immunological processes.

- PEA has a broad spectrum of biological targets and target molecules, among which are PPAR-alpha, TRPV1, and orphan receptors such as GPR-55.<sup>2</sup>
- **PPARalpha:** PPAR alpha agonists exert their anti-inflammatory effects primarily by suppressing pro-inflammatory mediators and antagonizing the pro-inflammatory functions of various cell types relevant to asthma pathophysiology. Also it acts via upregulation of anti-inflammatory mediators.<sup>3</sup>
- **TRPV1:** TRPV1 was overexpressed in the airway epithelium and submucosa of asthmatic patients compared with healthy controls suggesting that increased expression of TRPV1 is associated with disease pathophysiology in non-neuronal cell types.<sup>4</sup>
- **Proinflammatory enzymes:** PEA further reduces the activity of the proinflammatory enzymes such as cyclooxygenase, and endothelial, and inducible nitric oxide synthases.
- **Autacoid Effect:** ('ALIA' from 'Autacoid Local Inflammation Antagonist') Specifically, PEA is known mostly as an anti-inflammatory agent due to the downregulation of mediator release from mast cells, monocytes and macrophages.

## BOSWELLIA SERRATA-AKBA:

- Gum resin extracts of *Boswellia serrata* have been used for centuries for the treatment of chronic inflammatory diseases. AKBA (3-O-acetyl-11-keto- $\beta$ - boswellic acid), a pentacyclic triterpene, is the most potent anti-inflammatory fraction of the boswellic acids.
- Abundant scientific research shows that the AKBA fraction of Boswellic acids is ideally suited to inhibit the 5-lipoxygenase pathway and its resultant pathological inflammatory cascade and leukotriene biosynthesis.
- A human clinical double blind study was done on forty patients with chronic asthma. They were given 300 mg three times daily of a BSE for 6 weeks.
- 70% of patients showed improvement by the lowering of attack frequency, lowered eosinophilic counts, disappearance of dyspnea, rhonchi and an increase in pulmonary function, such as increase of FEV 1 and FVC. In the control group only 27% of patients showed improvement.<sup>5</sup>

## PINE BARK EXTRACT:

- About 65–75 % of the extract are procyanidins that consist of catechin and epicatechin subunits of varying chain lengths. It has shown diverse anti-inflammatory actions.
- A double-blind, placebo-controlled, cross-over study has investigated the effect of Pine bark extract in 22 patients, suffering from asthma since 1 and up to 16 years. Patients were randomly assigned to either the Pine bark group, receiving 1 mg/lb/day (without exceeding 200 mg/day), or to the group receiving placebo for 4 weeks.
- After 4 weeks' treatment with pine bark extract the patients could exhale 71% of their lung volume as compared to 59% at trial start and 63% in response to placebo, respectively.<sup>6</sup>

Parameter	Baseline	After Treatment	P value	Placebo Treatment	P value
%FEV1	59 $\pm$ 4.25	70 $\pm$ 5.01	P = 0.0008	63 $\pm$ 5.79	P=0.003
Mean cysteinyl-leukotriene	1044.66 $\pm$ 33.4	844.4 $\pm$ 32.4	P = 0.0001	1017.96 $\pm$ 28.2	P=0.003

- The improvement of airway function was paralleled by a reduction of leukotrienes, pro-inflammatory mediators, in the blood. Pine Bark extract treatment also significantly reduced serum leukotrienes compared with placebo.<sup>6</sup>

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## DESCRIPTION:

**PALMIRESP** is a tablet of unique anti-inflammatory combination as an adjuvant treatment in hyper responsiveness and chronic airway inflammation.

## COMPOSITION:

### Each Tablet contains:

Palmitoylethanolamide (PEA).....	300 mg
Boswellia Serrata Extract .....	300 mg
Pine Bark Extract.....	200 mg

## INDICATION:

As an anti-inflammatory adjuvant treatment in acute and Chronic Respiratory disorder such as asthma, COPD, Respiratory Tract Infections etc..

## MECHANISM OF ACTION:

- ✓ **PEA:** PEA has a broad spectrum of biological targets and target molecules, among which are PPAR-alpha, TRPV1, and orphan receptors such as GPR-55. PPAR $\alpha$  activation reduces production of multiple pro-inflammatory mediators, including tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), IL-1 $\alpha$ , IL-6, and IL-8 in chronic inflammatory conditions, such as those characterized by constitutive NF- $\kappa$ B activation and elevated levels of pro-inflammatory cytokines.
- ✓ **Boswellia Serrata Extract AKBA 30%:** the AKBA fraction of Boswellic acids is ideally suited to inhibit the 5-lipoxygenase pathway and its resultant pathological inflammatory cascade and leukotriene biosynthesis.
- ✓ **Pine Bark Extract:** Pine bark extract is rich in bioflavonoids and procyanidins that consist of catechin and epicatechin subunits of varying chain lengths. It has shown diverse anti-inflammatory actions and antioxidant effects.

## DOSE:

As Prescribed by healthcare practitioners.

## PRESENTATION:

It is available as 15 Tablets in a strip.

### References:

- 1) *Oxidative Medicine and Cellular Longevity*, Volume 2021, Article ID 6646923, 11 pages
- 2) *International Journal of Inflammation* Volume 2013
- 3) Banno et. al. *Nucl Receptor Res.* 2018
- 4) *Allergy Asthma Immunol Res.* 2018 May;10(3):187-185.
- 5) *Eur J Med Res.* 1998 Nov 17;3(11):511-4.
- 6) *Journal of Medicinal Food*, 4: 201-209, 2001.

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Prescribing Information



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