

Pidotimune

Pidotimod 400 mg and 800 mg Tablet

DESCRIPTION:

PIDOTIMUNE Tablets contains Pidotimod, a synthetic dipeptide molecule with immunomodulatory properties focused on both adaptive and innate immunity.

COMPOSITION:

PIDOTIMUNE-400

Each Film coated Tablet contains
Pidotimod - 400 mg

PIDOTIMUNE-800

Each Film coated Tablet contains
Pidotimod - 800 mg

MECHANISM OF ACTION:

Pidotimod works as immunostimulant by enhancing innate as well as adaptive immune responses.

INDICATIONS:

- Recurrent Upper & Lower Respiratory tract Infections in children and Adults
- Acute Respiratory tract infections
- Asthma
- Chronic Obstructive pulmonary Disorders
- Chronic bronchitis
- Immunological disorders

DOSAGE:

PIDOTIMOD is recommended for 60 days therapy in following dosing pattern:

Children: First 15 days: 400 mg twice daily
Remaining 45 days: 400 mg once daily

Adults: First 8 days: 800 mg twice daily
Rest 60 days: 800 mg once daily

PACKAGING:

PIDOTIMUNE - 400 & 800 available as 10 tablets in a strip.

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THE FORGOTTEN PANDEMICS:

At present, despite the introduction of new antibiotics and vaccines which contribute to reduce the risk of mortality and morbidity, they remain widespread and affect both young and elder people:

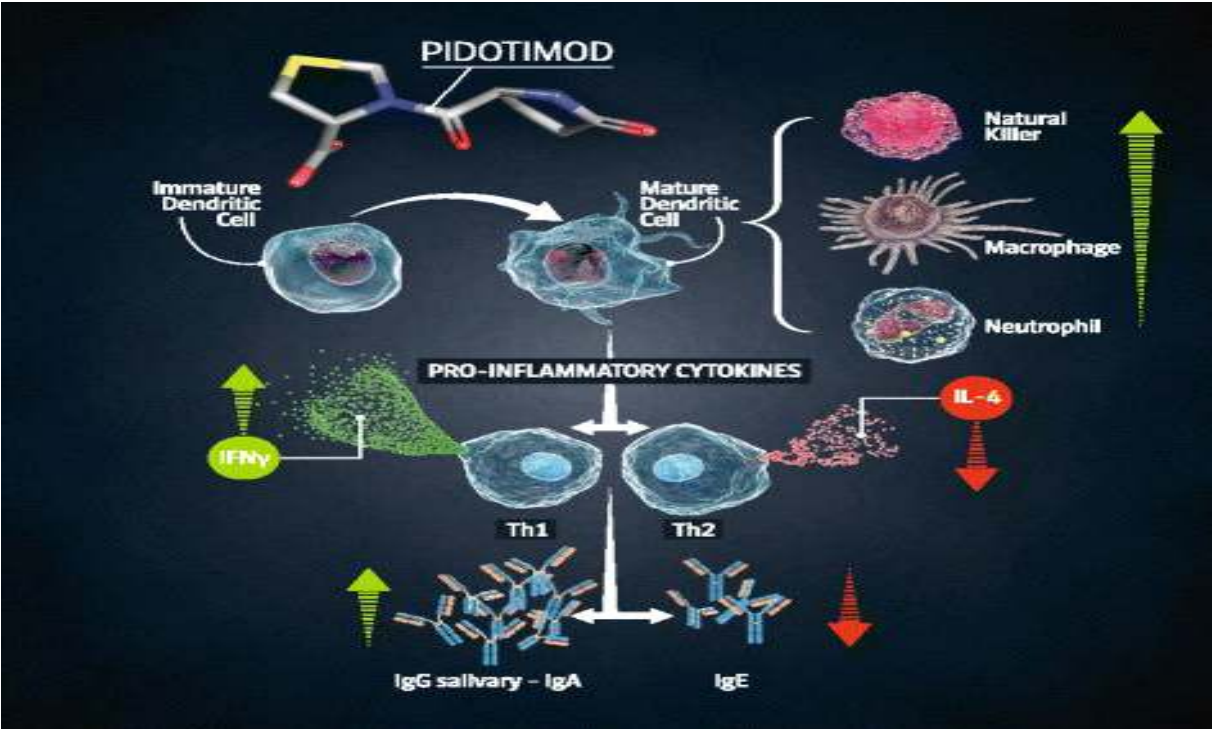
- Recurrent Respiratory Tract Infections
- Acute Respiratory Infections
- Asthma
- Chronic Obstructive Pulmonary Disorders
- Chronic Bronchitis

THE URGE OF IMMUNOSTIMULANT:

- Increased risk of exposure to infectious agents coupled with the immaturity of the immune system in Children
- The immune system, in fact, during senile age goes through age-associated alterations, defined as “immunosenescence” which lead to a lower ability to respond to infections and to develop immunity after vaccination
- Lower expression of toll-like receptors (TLRs) on epithelial cell membranes has been reported, and this leads to less efficient recognition of pathogens and a delayed and less effective induction of the innate immune response
- The activity of lymphocytes, macrophages, and dendritic cells is poor in the first years of life
- Socio-economic burden of ARTIs remains high, considering the cost of symptomatic drugs, antibiotics, hospitalization and the indirect cost of absence from work or loss of school days.

PIDOTIMOD:

- 3-L-pyroglutamyl-L-thiazolidine-4carboxylic acid is a synthetic dipeptide molecule with immunomodulatory properties focused on both adaptive and innate immunity.



- Higher expression of TLR2 and of HLA-DR molecules
- Induction of dendritic cell maturation and release of pro-inflammatory molecules
- Stimulation of T lymphocyte proliferation and differentiation toward a Th1 phenotype
- Enhances natural killer (NK) cells functions and Promotes phagocytosis.

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CLINICAL EVIDENCE

IMMUNOMODULATORY EFFECTS OF PIDOTIMOD IN ADULTS WITH COMMUNITYACQUIRED PNEUMONIA UNDERGOING STANDARD ANTIBIOTIC THERAPY

Group of Patients: Sixteen patients with a diagnosis of CAP and a PSI score III or IV and/or a CURB-65 0-2

Study Group(PDT): Levofloxacin plus Pidotimod (800mg, 2 daily doses).

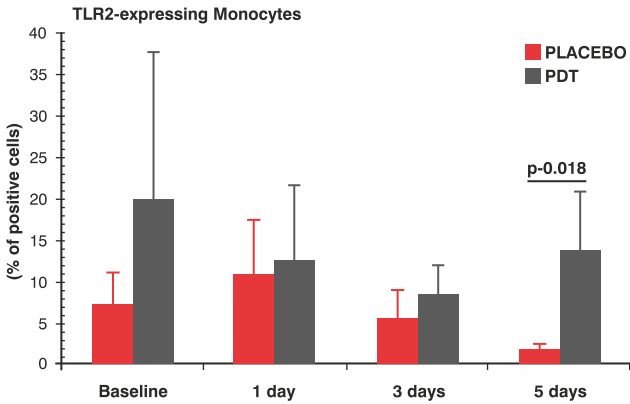
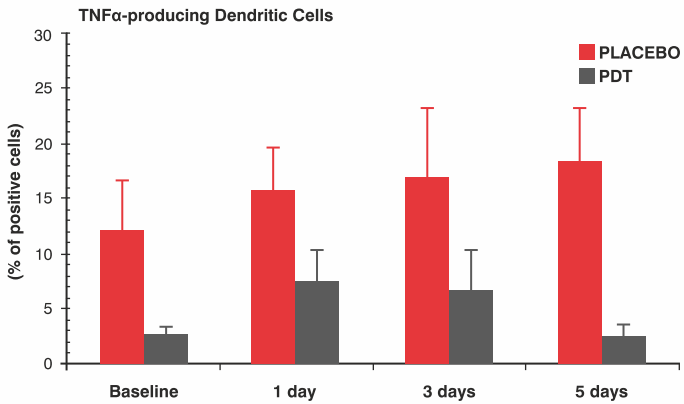
Control Group: Only Standard Antibiotics(Levofloxacin 500 mg b.i.d. alone)

Evaluation: At the time of recruitment (T0) (i.e., before therapy administration) , at T3 and T5 (i.e., 3 and 5 days after the initiation of therapy).

Immunologic and clinical parameters were analyzed at each time point.

Results:

- **Effects of pidotimod on antibacterial and immunomodulatory proteins**
Significantly Upregulated by number of genes in PDT group
- **Modulation of TLR2 and TLR4 expression by pidotimod**
Results showed that TLR2- and TLR4-expressing Cd14 β cells (monocytes) were significantly increased in patients in PDT group



- **Effects of pidotimod on inflammatory proteins**
Genes responsible for the generation of cytokines (CCL and CXL) as well as those for the inflammatory cytokines IL1 and TNF-α were down regulated.
- **Modulation of HLA class II and CD80 and CD86 expression by pidotimod**
Results indicate that HLA class II expressing DC were increased, indicating that antigen presentation might be improved by pidotimod.

The percentage of CD80- and CD86-expressing DC was increased significantly as well at day 3 in the PDT (P < 0.05). Because CD80 and CD86 are key proteins in initiating B-T lymphocyte collaboration and in the generation of antibodies

Conclusion: These results confirm that supplementation of antibiotic therapy with Pidotimod in patients with CAP results in a potentially beneficial modulation of innate immunity