Biocon

Pimecrolimus Solution 1% w/v

PICON® *Lotion* पाइकौन लोशन

COMPOSITION
Each ml contains:
Pimecrolimus 10 mg
In base q.s.

PHARMACEUTICAL FORM
Topical solution

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic Properties
Pharmacotherapeutic group: Agents for dermatitis, excluding corticosteroids.
ATC code: D11AH02

Mechanism of Action
The mechanism of action of pimecrolimus in atopic dermatitis is not known. While, it has been demonstrated that pimecrolimus binds with high affinity to macrophilin-12 (FKBP-12) and inhibits the calcium-dependent phosphatase, calcineurin. As a consequence, it inhibits T cell activation by blocking the transcription of early cytokines. In particular, pimecrolimus inhibits (at nano molar concentrations) interleukin-2 and interferon gamma (Th 1-type) and interleukin-4 and interleukin-10 (Th2-type) cytokine synthesis in human T cells. In addition, pimecrolimus prevents the release of inflammatory cytokines and mediators from mast cells *in vitro* after stimulation by antigen Ig E.

Clinical Safety and Efficacy Studies
The clinical studies reported in literature with pimecrolimus 1% cream are briefed below.
Three randomized, double-blind, vehicle-controlled, multicenter, phase 3 studies were conducted in 589 pediatric patients, aged 3 months to 17 years to evaluate pimecrolimus 1% cream for the treatment of mild to moderate atopic dermatitis. Two of the three trials support the use of pimecrolimus cream in patients 2 years and older with mild to moderate atopic dermatitis (see **Special Warnings and Precautions for Use** and **Therapeutic Indication** sections). Three other long term trials in 1,619 pediatric and adult patients provided additional data regarding the safety of pimecrolimus cream in the treatment of atopic dermatitis. Two of these other trials were vehicle -cont rolled with optional sequential use of a medium potency topical corticosteroid in pediatric patients and one trial was an active comparator study in adult patients with atopic dermatitis. These studies showed a significant reduction in the incidence of flares ($p<0.001$) in favor of pimecrolimus 1% cream treatment. Pimecrolimus treatment showed better efficacy in all secondary assessments like eczema area severity index, investigators global assessment, subject assessment and pruritus was found to be controlled within a week with pimecrolimus. Most of the children and infants treated with pimecrolimus 1% cream completed 6 and 12 months respectively with no reported flare. Pimecrolimus was also found to be having a sparing effect on the use of topical corticosteroids as most children and infants treated with pimecrolimus did not use corticosteroids in 12 months.

CLINICAL PARTICULARS
Therapeutic Indications
Topical pimecrolimus is indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immuno-compromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.

Posology and Method of Administration
Apply least required quantity of Pimecrolimus to the affected skin areas twice daily and rub in gently and completely. Pimecrolimus may be used on all skin areas, including the head and face, neck and intertriginous areas, except on mucous membranes. Each affected region of the skin should be treated with Pimecrolimus until clearance occurs and then treatment should be discontinued. Stop the treatment if there is no improvement after 6 weeks or if there is worsening of eczema. Patients should be re-exammed to confirm the diagnosis of atopic dermatitis if the signs and symptoms persist beyond 6 weeks. Pimecrolimus should not be applied under occlusion (see **Special Warnings and Precautions for Use** section). Emollients can be applied immediately after using Pimecrolimus.

Contraindications
Patients with hypersensitivity to pimecrolimus or to any of the products excipients.

Special Warnings and Precautions for Use
General
Long-term safety of topical calcineurin inhibitors has not been established. Although a causal relationship has not been established, rare cases of malignancy (eg, skin and lymphoma) have been reported in patients treated with topical calcineurin inhibitors, including pimecrolimus. Therefore continuous long-term use of topical pimecrolimus, in any age group should be avoided, and application is limited to areas of involvement with atopic dermatitis. Safety of usage of topical pimecrolimus beyond 1 year is not established.
Topical pimecrolimus is not indicated for use in children less than 2 years of age.
The use of topical pimecrolimus should be avoided on malignant or pre-malignant skin conditions such as cutaneous T-cell lymphoma (CTCL), can present as dermatitis.
Topical pimecrolimus should not be used in patients with Netherton's syndrome or other skin diseases where there is the potential for increased systemic absorption of pimecrolimus. The safety of topical pimecrolimus has not been established in patients with generalized erythroderma.
The use of topical pimecrolimus may cause local symptoms such as skin burning (burning sensation, stinging, soreness) or pruritus. Localized symptoms are most common during the first few days of pimecrolimus topical application and typically improve as the lesions of atopic dermatitis resolve(see **Undesirable Effects** section).
Care should be taken to avoid contact with eyes and mucous membranes. If accidentally applied to these areas, it should be thoroughly wiped off and/or rinsed off with water.
The use of topical pimecrolimus under occlusion has not been studied in patients. Therefore, occlusive dressings are not recommended.

Bacterial and Viral Skin Infections
Treatment with topical pimecrolimus may be independently associated with an increased risk of varicella zoster virus infection (chicken pox or shingles), herpes simplex virus infection, or eczema herpeticum. Patients with severe atopic dermatitis may also have an increased risk of skin bacterial infections(impetigo) during treatment with Pimecrolimus. In cases of worsening of skin papillomas or no response to conventional therapy, discontinuation of Pimecrolimus should be considered until complete resolution of the warts is achieved.

Patients with Lymphadenopathy
Patients who receive topical pimecrolimus and who develop lymphadenopathy should have the etiology of their lymphadenopathy investigated. In the absence of a clear etiology for the lymphadenopathy, or in the presence of acute infectious mononucleosis, topical pimecrolimus should be discontinued. Patients who develop lymphadenopathy should be monitored to ensure that the lymphadenopathy resolves.

Only for the use of a Registered Medical Practitioner or a Hospital or a Laboratory.

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Sun Exposure
During the course of treatment, it is prudent for patients to minimize or avoid natural or artificial sunlight exposure, even while Pimecrolimus is not applied. The potential effects of topical pimecrolimus on skin response to ultraviolet damage are not known.

Immuno-compromised Patients
The safety and efficacy of topical pimecrolimus in immune-compromised patients have not been studied.

Drug Interactions
Potential interactions between pimecrolimus and other drugs, including immunizations, have not been systematically evaluated. The concomitant administration of known CYP3A family of inhibitors like erythromycin, itraconazole, ketoconazole, fluconazole, calcium channel blockers and cimetidine in patients with widespread and/or erythrodermic disease should be done with caution.

Pregnancy and Lactation
Pregnancy: Category C, there are no adequate and well-controlled studies of topically administered pimecrolimus in pregnant women. Therefore, this drug should be used only if clearly needed during pregnancy.
Lactation: It is not known whether this drug is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from pimecrolimus, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Effects on Ability to Drive and Use Machines
Topical pimecrolimus has no known effect on the ability to drive and use machines.

Undesirable Effects
The most common adverse events reported in patients treated with pimecrolimus 1% cream were application site reactions (application site burning, irritation, pruritus and erythema) , skin infections (folliculitis), malignancy (including cutaneous and other types of lymphoma, skin cancers) and lymphadenopathy.

Overdose
There has been no reported experience of overdose with topical pimecrolimus.If oral ingestion of pimecrolimus occurs, medical advice should be sought.

Instructions for patients
Patients using Topical pimecrolimus should receive following information and instructions:
- Patients should use Topical pimecrolimus as directed by physician. Topical pimecrolimus is for use on the skin only (topical). Do not get it in to your eyes, nose, mouth, vagina, or rectum. Use Topical pimecrolimus only on areas of your skin that have eczema. Do not use Topical pimecrolimus continuously for a long time.
- As with any topical medication, patients or care givers should wash hands after application if hands are not an area for treatment.
- Patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using Topical pimecrolimus.
- Patients should not use this medication for any disorder other than that for which it was prescribed.
- Patients should report any signs of adverse reactions to their physician.
- Before applying Topical pimecrolimus after a bath or shower, be sure your skin is completely dry.

PHARMACEUTICAL PARTICULARS
Incompatibilities
This medicinal product must not be mixed with any other medicinal products.

Shelf Life: Please refer carton/label.

Storage and Precautions
Storage: Store at a temperature not exceeding 30°C, away from light & moisture.
Do not refrigerate or freeze.
Flammable. Keep the solution away from fire or flame.
It is for topical dermatological use only. Not for ophthalmic use.
Close the flip top cap tightly after use.
Keep out of reach of children.

Special Precautions for Disposal and Other Handling
Not specified.

Nature and Contents of Container
PICON® *Lotion* is supplied as a 20 mL HDPE white flat bottle with HDPE flip top cap.

BF/LL/3702/01

Marketed by:
Biocon Biologics India Limited
Biocon House, Semicon Park,
Electronics City, Phase - II,
Bengaluru - 560 100, India.

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To report adverse events and/or product complaints visit our website **www.biocon.com** or call toll free number: **1800 102 9465** or e-mail us at **drugsafety@biocon.com**