1.3 Product Information

1.3.1 Summary of Product characteristic

1. Name of the medicinal product

JACYBARCT CREAM

2. Qualitative and quantitative composition

Clobetasol Propionate USP.....0.05% W/W

Clotrimazole USP.....1.0%

Excipients(s) with known effect

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

White coloured Cream

4. Clinical particulars

4.1 Therapeutic indications

JACYBARCT CREAM is indicated for the local treatment of oropharyngeal candidiasis, eczema and psoriasis and vaginal yeast infections, also used in fungal infections of the skin such as ringworm, athlete's foot, and jock itch. It is also highly effective for contact dermatitis caused by exposure to poison ivy/oak.

4.2 Posology and method of administration

Posology

A thin film of Cream should be applied to cover completely the affected area two or three times daily, or as prescribed by the physician.

Method of administration

Applied over the affected area

4.3 Contraindications

Long-term treatment of ulcerative conditions, rosacea, pruritus; presence of acute infections Hypersensitivity.

4.4 Special warnings and precautions for use

General: Clotrimazole; should be used cautiously during pregnancy. It should be used with caution in patients with medical history or allergies. Topical application of clotrimazole is contraindicated in children under the age of 2, unless recommended by the physician.

Clobetasol propionate is a highly potent topical corticosteroid that has been shown to suppress the HPA axis at doses as low as 2 g per day. Systemic absorption of topical corticosteroids has resulted in reversible HPA axis suppression, manifestations of Cushing' syndrome, hyperglycemia, and glucosuria in some patients. Conditions that augment systemic absorption include the application of the more potent corticosteroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity If irritation develops, topical corticosteroids should be discontinued, and appropriate therapy instituted.

4.5 Interaction with other medicinal products and other forms of interaction

No drug-drug interactions were noted in the clinical studies presented.

4.6 Fertility, pregnancy and lactation

The more potent corticosteroids have been shown to be teratogenic in animals after dermal application. Clobetasol propionate has not been tested for teratogenicity by this route; however, it is absorbed percutaneously, and when administered subcutaneously it was a significant teratogen in both the rabbit and the mouse. Clobetasol propionate has greater teratogenic potential than steroids that are less potent. There are no adequate and well-controlled studies of the teratogenic effects of topically applied corticosteroids, including clobetasol, in pregnant women. Therefore, clobetasol and other topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus, and they should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

4.7 Effects on ability to drive and use machines

No clinical studies information is available regarding the product’s effect on ability to drive and use machines.

4.8 Undesirable effects

Burning sensation, stinging sensation, Erythema, stinging, irritation; hypersensitivity reactions; contact dermatitis, and itching of skin may occur on applied portion which disappear shortly after application.

4.9 Overdose

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercorticism may appear and in this situation topical steroids should be discontinued.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group

Anti-inflammatory, Antifungal ATC code: G01AF02, D07AD01

Mechanism of action:

Clobetasol propionate Like other topical corticosteroids, has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

Clotrimazole alters the permeability of the fungal cell wall and inhibits the activity of enzymes within the cell. It specifically inhibits the biosynthesis of ergosterol and other sterols required for cell membrane production. Clotrimazole may also inhibit endogenous respiration, interact with membrane phospholipids, inhibit the transformation of yeasts to mycelial forms and the uptake of purine, impair triglyceride and/or phospholipid biosynthesis, and inhibit the movement of calcium and potassium ions across the cell membrane by blocking the ion transport pathway known as the Gardos channel.

5.2 Pharmacokinetic properties

Clobetasol propionate: The extent of percutaneous absorption of topical corticosteroids, including clobetasol propionate, is determined by many factors, including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings. As with all topical corticosteroids, clobetasol propionate can be absorbed from normal skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Once absorbed through the skin, topical corticosteroids enter pharmacokinetic pathways similarly to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids, including clobetasol propionate and its metabolites, are also excreted into the bile. This Cream has been shown to depress the plasma levels of adrenal cortical hormones following repeated nonocclusive application to diseased skin in patients with psoriasis and eczematous dermatitis. These effects have been shown to be transient and reversible upon completion of a two-week course of treatment.

Clotrimazole: Pharmacokinetic investigations after dermal application have shown that clotrimazole is practically not absorbed from intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.01 microg / ml, reflecting that clotrimazole applied topically does not lead to measurable systemic effects or side effects

5.3 Preclinical safety data
None stated.

6. Pharmaceutical particulars

6.1 List of excipients

Cetostearyl Alcohol
Cetomacrogol 1000
White soft Paraffin
Light Liquid Paraffin
Para Chloro Meta Cresol
Di Sodium Hydrogen orthophosphate
Sodium Di Hydrogen orthophosphate
Purified water
Disodium EDTA
Propylene Glycol
Papaya Fragrance

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
2 years.

6.4 Special precautions for storage
Store in cool and dry place, protect from light.

6.5 Nature and contents of container
Cream is packed in laminated tube

6.6 Special precautions for disposal and other handling
No special requirements.

7. Manufacturer / Applicant

Medisky Pharmaceuticals Private Limited
Plot No: 260 G.I.D.C. Talod- 383215, Dist:
Sabarkantha, Gujarat.