1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC): Enclosed

1. NAME OF THE MEDICINAL PRODUCT:

FOTAX CREAM (Ketoconazole, Clobetasol Propionate & Neomycin Sulfate Cream)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each gm Contains:

Ketoconazole BP……..…….10.0 mg

Clobetasol Propionate USP ...…….…..0.25 mg

Neomycin Sulfate USP ……5000 IU

Cream Base…….…….....….. Q.S.

3. PHARMACEUTICAL FORM: TOPICAL CREAM

A white to off white smooth Perfumed cream

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

Antifungal, Anti-inflammatory, Antibacterial

Clobetasol propionate is a very active topical corticosteroid which is of particular value when used in short courses for the treatment of more resistant dermatoses such as psoriasis (excluding widespread plaque psoriasis), recalcitrant eczemas, lichen planus, discoid lupus erythematosus, and other skin conditions which do not respond satisfactorily to less active steroids.

Ketoconazole, an imidazole-piperazine compound, is an orally active antimycotic agent. In addition, ketoconazole is a specific inhibitor of cytochrome P450 3A4.

Neomycin is an aminoglycoside class of antibiotics that contain two or more amino sugars connected by glycosidic bonds. Neomycin Sulphate is used to prevent and treat bacterial infections of the skin.

4.2 Posology and method of administration

-Oral

-Intravenous

-Intramuscular

-Topical

-Inhalation

-Others

4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients. The following conditions should not be treated with Fotax Cream :

- Untreated cutaneous infections
- Rosacea
- Acne vulgaris
- Pruritus without inflammation
- Perianal and genital pruritus
- Perioral dermatitis.

Clobetasol is contraindicated in dermatoses in children under one year of age, including dermatitis and nappy eruptions.

4.4 Special warnings and precautions for use

Fotax Cream (Ketoconazole, Clobetasol Propionate & Neomycin Sulfate Cream) is not for ophthalmic use.

Suitable precautions should be taken if extensive body surface areas are treated, occlusive technique is used, or when long term use is anticipated, particularly in infants and children. Prolonged use of topical antibiotics may result in overgrowth of non-susceptible organisms, irritation, sensitization or super infection develops, if this occurs, treatment with Fotax Cream (Ketoconazole, Clobetasol Propionate & Neomycin Sulfate Cream) should be discontinued and appropriate therapy instituted.

4.5 Interaction with other medicinal products and other forms of interaction

Pregnancy: Teratogenic Effects: Pregnancy Category C: Although there is no evidence of risk to the foetus, caution is advised during pregnancy and lactation.

4.6 Fertility, pregnancy and lactation

Clobetasol Propionate:

There are limited data from the use of clobetasol in pregnant women.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development.

The relevance of this finding to humans has not been established. Administration of clobetasol during pregnancy should only be considered if the expected benefit to the mother outweighs the risk

to the foetus. The minimum quantity should be used for the minimum duration.

The safe use of topical corticosteroids during lactation has not been established.

It is not known whether the topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. Administration of clobetasol during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

If used during lactation clobetasol should not be applied to the breasts to avoid accidental ingestion by the infant.

There are no data in humans to evaluate the effect of topical corticosteroids on fertility

Clobetasol administered subcutaneously to rats had no effect upon mating performance; however, fertility was decreased at the highest dose.

Neomycin Sulfate:

The manufacturer makes no recommendation regarding use during pregnancy and lactation for Neomycin Sulfate. USFDA pregnancy category: Not formally assigned to a pregnancy category.

Animal studies have not been reported. There are no controlled data in human pregnancy.

Ketoconazole:

There are no adequate and well-controlled studies in pregnant or lactating women. Data on a limited number of exposed pregnancies indicate no adverse effects of topical ketoconazole on pregnancy or on the health of the foetus/newborn child. Animal studies have shown reproductive toxicity at doses that are not relevant to the topical administration of ketoconazole.

4.7 Effects on ability to drive and use machines

The medicinal product has no influence on the ability to drive or operate machinery

4.8 Undesirable effects

Common side effects include skin conditions like itching, burning, stinging, dryness, scaly patches and redness.

Seek medical attention if any adverse effects occur.

For a comprehensive list of all possible effects, consult your doctor.

If any symptom persists or gets worse, or you notice any other symptom, then please call your doctor immediately.

4.9 Overdose

Antifungal, Anti-inflammatory, Antibacterial

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5. Pharmacological properties

5.1 Pharmacodynamic properties

Mechanism of Action:

Clobetasol Propionate is topical corticosteroids act as anti-inflammatory agents via multiple mechanisms to inhibit late phase allergic reactions including decreasing the density of mast cells, decreasing chemotaxis and activation of eosinophils, decreasing cytokine production by lymphocytes, monocytes, mast cells and eosinophils, and inhibiting the metabolism of arachidonic acid.

Neomycin Sulfate actively transported across the bacterial cell membrane, binds to a specific receptor protein on the 30 S subunit of bacterial ribosomes, and interferes with an initiation complex between mRNA (messenger RNA) and the 30 S subunit, inhibiting protein synthesis. DNA may be misread, thus producing non-functional proteins; polyribosomes are split apart and are unable to synthesize protein.

In vitro studies suggest that ketoconazole impairs the synthesis of ergosterol, which is a vital component of fungal cell membranes. It is postulated that the therapeutic effect of ketoconazole in seborrheic dermatitis is due to the reduction of M. ovale, but this has not yet been proven.

5.2 Pharmacokinetic properties

Ketoconazole: When cream was applied dermally to intact or abraded skin of beagle dogs for 28 consecutive days at a dose of 80 mg, there were no detectable plasma levels using an assay method having a lower detection limit of 2 mg/mL. After a single topical application to the

chest, back and arms of normal volunteers, systemic absorption of ketoconazole was not detected at the 5 ng/mL level in blood over a 72-hour period. Two dermal irritancy studies, a human sensitization test, a phototoxicity study and a photo allergy study conducted in 38 male and 62 female volunteers showed no contact sensitization of the delayed hypersensitivity type, no irritation, no phototoxicity and no photo allergenic potential due to cream.

Clobetasol Propionate: The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusive dressing with hydrocortisone for up to 24 hours has not been demonstrated to increase penetration; however, occlusion of hydrocortisone for 96 hours markedly enhances penetration. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

Neomycin Sulfate: Although not absorbed through intact skin, topical neomycin is readily absorbed from large denuded, burned, or granulating areas.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Emulsifying Wax	USP/NF
Cetostearyl Alcohol	BP
White Soft Paraffin	BP
Methyl Paraben	BP
Propyl Paraben	BP
Propylene Glycol	BP
Disodium Hydrogen Phosphate	BP
Isopropyl Myristate	BP
Light Liquid Paraffin	BP
Dimethicone 350	BP
SATR 10	INH
Sodium Metabisulfite	BP
Citric Acid	BP

Perfume B 3309	INH
Vitamin E Acetate	BP
Sodium Acid Phosphate	BP
Purified Water	BP

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C., Protect from light. Do not refrigerated. Keep out of the reach of children.

6.5 Nature and contents of container

The cream is filled into lami tubes with white colour stand-up caps and enclosed in an outer carton. Pack sizes available are 15g.

6.6 Special precautions for disposal and other handling

Not applicable.

ADMINISTRATIVE DATA:

7. Marketing authorisation holder

Kremoint Pharma Pvt. Ltd.,
B-8 Additional MIDC, Ambernath
Ambernath (E). Thane 421506
Maharashtra, India.

8. Marketing authorisation number(s):

28-KD/146

9. Date of first authorisation/renewal of the authorisation

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10. Date of revision of the text:
