1. NAME OF THE MEDICINAL PRODUCT

TIATIO CREAM 30 G (Clobetasol Cream USP 0.05% w/w)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Clobetasol Propionate USP .....0.05% w/w

Cream base.....q. s.

Batch Size: 1000kg

UNITFORMULA

INGREDIENTS	Label claim	OVERAGES	QTY/BATCH(KG)	REFERENCE
Clobetasol Propionate	0.05% w/w	2%	0.1581	USP
Chlorocresol	0.1%	--	0.310	
Light Liquid Paraffin	10%	--	31.00	BP
Hard Paraffin Wax	2%	--	6.200	
Microcrystalline Wax	1.5%	--	18.600	BP
BHT	0.05%	--	0.155	
CetoSteryl Alcohol	7%	-	21.700	
Cetomacrogol-1000	2%	--	6.200	BP
Methyl Paraben	0.16%	--	0.496	BP
Propyl Paraben	0.040%		0.124	
Disodium EDTA	0.1%	--	0.310	BP
Col.Erythrocin (Supra)	--	--	2.480	BP
Col Panceau 4 R (Supra)	--	--	1.240	BP
Glycerine	1%		3.00	
Propylene Glycol	1.612%		5.00	
Perfume Ponds	0.12%		0.372	
Purified Water	--	--	QS to 310 Kg	BP

3. PHARMACEUTICALFORM

Topical

4. Clinical particulars

Indication

It is indicated in resistant dermatoses where secondary bacterial infection and/or fungal infection is present suspected, or likely to occur.
e.g., psoriasis (excluding wide spread plaque psoriasis), recalcitrant eczemas

Posology and Administration
Adults and adolescents
Apply thinly and gently rub in using only enough to cover the entire affected area twice daily until improvement occurs.
The maximum weekly dose should not exceed 50g/week.

Contraindications

Hypersensitivity to the cephalosporin or to any of the excipients.

Special warnings and precautions for use
No special warning.

Interaction with other medicinal products and other forms of interaction
Co-administered drugs that can inhibit CYP3A4 (e.g. ritonavir and itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

Pregnancy and Lactation

The minimum quantity should be used for the minimum duration.

Effects on ability to drive and use machines
Not applicable.

Undesirable effects
None known
Overdose
Not applicable

5. PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamic properties

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 o farachidonic acid.

CLOBETASOLactsagainstfungibyinhibitingergosterolsynthesis.Inhibitionofergosterolsynthesisleadstostructuralandfunctionalimpairmentofthecytoplasmicmembrane.

Pharmacokinetic properties
CLOBETASOL

Absorption
Percutaneouspenetrationofclobetasolpropionatevariesamongindividualsandcanbeincreased by the use of occlusive dressings, or when the skin is inflamed or diseased.

Distribution
Mean peak plasma clobetasol propionate concentrations of0.63ng/ml occurred in one study 8 hours after the second application (13 hours after an initial application) of 30 g clobetasol propionate 0.05% ointment to normal individuals with healthy skin.Following the application of a second dose of 30 g clobetasol propionate cream 0.05 % mean peak plasma concentrations were slightly higher than the ointment and occurred10 hours after application.
Inaseparatestudy,meanpeakplasmaconcentrationsofapproximately2.3ng/mland4.6ng/mloccurred respectively in patients with psoriasis and eczema 3 hours after a single application of 25g clobetasol propionate0.05 %ointment.
Clobetasol propionate is extensively bound to plasma proteins (>90%) and has as mall volume of distribution.

Metabolism
Following percutaneous absorption of clobetasol propionate the drug probably follows the metabolic pathway of systemically administered corticosteroids. They are metabolized primarily in the liver. However, systemic metabolism of clobetasol propionate has never been fully characterized or quantified.
Elimination
Topical corticosteroids are excreted by the kidneys.Inaddition,some corticosteroids and their metabolites are also excreted in the bile.

CLOBETASOL

CLOBETASOL is minimally absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of CLOBETASOL were below the detection limit of 0.001 mcg/ml, suggesting that CLOBETASOL applied topically is unlikely to lead to measurable systemic effects or side effects.

Preclinical safety data

None Stated

6. PHARMACEUTICAL PARTICULARS

List of excipients

Liquid light paraffin
White soft paraffin
Cetomacrogol1000
CetoStearyl Alcohol

Incompatibilities

Not applicable

Shelf life

36 months from the date of manufacture

Special precautions for storage

Store below 30ºC. Protect from light.

Nature and contents of container

30gm tube in a carton along with insert.

Special precautions for disposal<and other handling

No special requirement

7. <APPLICANT/MANUFACTURER>

MANUFACTURER

Ohad Pharmaceuticals Pvt. Ltd.
Plot no. 222 & 223, GIDC,
Industrial Estate, Palej – 392220,
District: Bharuch, Gujarat, India.

MARKETED BY

EVERDESTINY PHARMACEUTICALS LTD.
Lagos, Nigeria.