1.1 Name of the medicinal product: CLOBESTASOL PROPRIONATE CREAM USP 0.05%

1.2 Qualitative and quantitative composition:
Composition
Each gram Contains:
Clobetasol Propionate USP 005% w/w
Cream Base (QS)

Sr. No.	Ingredients	Specifi - cation	Label Claim w/w	Over- ages added (In %)	Quantity in % w/w	Reason for Function
1.	Clobetasol Propionate	USP	0.05% w/w	5%	0.0525%	Medicament
2.	Light liquid paraffin	BP	NA	NA	12.820%	Emollient
3.	Propylene Glycol	BP	NA	NA	4.000%	Solvent
4.	Hard paraffin Wax	BP	NA	NA	3.000%	Emollient
5.	Micro Crystalline Wax	IH	NA	NA	1.000%	Thickening agent
6.	Cetosteryl Alcohol	BP	NA	NA	8.000%	Thickening Agent, Stabilizing Agent
7.	Benzyl Alcohol	BP	NA	NA	1.000%	Preservative
8.	Cetomacrogol 1000	IH	NA	NA	2.000%	Emollient
9.	Chlorocresol	USP	NA	NA	0.100%	Preservative
10.	Butylated Hydroxytoluene	BP	NA	NA	0.050%	Preservative
11.	Tartrazine Supra	IH	NA	NA	0.006%	Colouring agent
12.	LRL Lemon Flavour	IH	NA	NA	0.300%	Colouring agent
13.	Lemon Extract	IH	NA	NA	1.000%	Colouring agent
14.	Purified Water	BP	NA	NA	66.680%	Vehicle

1.3 Pharmaceutical form: Cream

Description: Yellow coloured cream

1.4 Clinical Particulars
4.1 Therapeutic indications
CLOBESTASOL PROPRIONATE CREAM USP 0.05% is used to help reduce the redness and itchiness of certain skin problems. These skin problems include:
- frequently relapsing eczema
- psoriasis (thickened patches of inflamed, red skin, often covered by silvery scales), excluding widespread plaque psoriasis
- lichen planus, (a skin disease that causes itchy, reddish-purple, flat-topped bumps on the wrists, forearms or lower legs)
- discoid lupus erythematosus (a disease of the skin most often affecting the face, ears and scalp causing scarring and increased sensitivity of the affected skin to sunlight)
- dermatitis and other skin conditions that have not responded to milder steroid creams or ointments.

4.2 Posology and method of administration

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Using this medicine

• You usually apply a thin layer of **CLOBETASOL PROPIONATE CREAM USP 0.05 %** once or twice a day. This may be reduced as your skin begins to get better, or stopped when better. Your doctor may prescribe a weaker steroid for you to use instead.

• If you are also using an emollient (moisturiser), allow time for **CLOBETASOL PROPIONATE CREAM USP 0.05 %** to be absorbed into your skin before applying the emollient.

• This cream is for external use only.

• Do not use for more than 4 weeks without talking to your doctor. If you need treatment for a long time, your doctor may decide you need to use a milder cream or ointment.

• If you are applying the cream on someone else make sure you wash your hands after use or wear disposable plastic gloves.

4.3 Contraindications

CLOBETASOL PROPIONATE CREAM USP 0.05 % is contraindicated in

Patient having allergic (hypersensitive) to clobetasol propionate or any of the other ingredients of this medicine.

• on a child under the age of 1 year.

• to treat any of the following skin problems, it could make them worse:

- acne
- rosacea (severe flushing of skin on and around your nose, cheeks, chin, forehead or entire face with or without tiny visible blood vessels, bumps (papules) or pus-filled bumps (pustules))
- spotty red rash around your mouth (perioral dermatitis)
- itching around the anus or genitals (penis and vagina)
- infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
- itchy skin which is not inflamed
- widespread plaque psoriasis, except single lesions

4.4 Special warnings and precautions for use

• you experience newly developed bone pain or worsening of previous bone symptoms during a treatment with CLOBETASOL PROPIONATE CREAM USP 0.05 % especially if you have been using CLOBETASOLPROPIONATE CREAM USP0.05 % for a prolonged time or repeatedly.

• you use other oral/topical medication containing corticosteroids or medication intended to control your immune system (e.g. for autoimmune disease or after a transplantation). Combining CLOBETASOL PROPIONATE CREAM USP 0.05 % with these medicines may result in serious infections.

• you have previously had an allergic reaction with another steroid.

• you are applying the cream under an airtight dressing, including a child's nappy. These dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally end up using too much cream.

• make sure that the skin is cleansed before a fresh dressing is applied to prevent infections.

• you are applying the cream on broken or damaged skin or within skin folds.

• you are applying to a large surface area.

• you have psoriasis your doctor will want to see you more often.

• you are using around a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection.

Contact your doctor if you experience blurred vision or other visual disturbances.

4.5 Interaction with other medicinal products and other forms of interaction

Do not use clobetasol together with other topical corticosteroid containing medicines, such as betamethasone, hydrocortisone and triamcinolone. Using these medicines together may cause serious unwanted effects, you should always consult your doctor if you are taking other medicines for treating other health conditions.

4.6 Pregnancy and Lactation
Pregnancy
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.
Lactation
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.

4.7 Effects on ability to drive and use machines
There have been no studies to investigate the effect of clobetasol on driving performance or the ability to operate machinery.

4.8 Undesirable effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.
Stop using CLOBETASOL PROPIONATE CREAM USP 0.05 % and tell your doctor immediately if:
• you find that your skin problem gets worse, you develop a generalized rash or your skin becomes swollen during treatment. You may be allergic to the cream, have an infection or need other treatment.
• you have psoriasis and get raised bumps with pus under the skin. This can happen during or after the treatment and is known as pustular psoriasis.

Other side effect you may notice when using **CLOBETASOL PROPIONATE CREAM USP0.05 %** include:
Common (may affect up to 1 in 10 people)
A feeling of burning, pain, irritation or itching where the cream is applied.
Uncommon (may affect up to 1 in 100 people)
Skin thinning, this may cause stretch marks, blood vessels under the surface of your skin may become more noticeable.
Very Rare (may affect up to 1 in 10,000 people)
Moon face, rounding of the face, obesity, skin thinning, skin wrinkling, skin dryness, changes to the colour of your skin, increased body hair, hair loss/lack of hair growth/damaged looking hair

4.9 Overdose
Symptoms
Topically applied clobetasol may be absorbed in sufficient amounts to produce systemic effects. Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may occur (see section 1.3.1.4.8).
Management
In the event of overdose, clobetasol should be withdrawn gradually by reducing the frequency of application or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency.
Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

5 Pharmacological properties
5.1 Pharmacodynamic properties
Mechanism of action
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.

Pharmacodynamic effects
Topical corticosteroids, have anti-inflammatory, antipruritic, and vasoconstrictive properties.

5.2 Pharmacokinetic properties
Absorption
Topical corticosteroids can be systemically absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier.
Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption.
Mean peak plasma clobetasol propionate concentrations of 0.63 ng/ml occurred in one study eight 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 occurred 10 hours after application.
In a separate study, mean peak plasma concentrations of approximately 2.3 ng/ml and 4.6 ng/ml occurred respectively in patients with psoriasis and eczema three hours after a single application of 25 g clobetasol propionate 0.05% ointment.
Distribution
The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary due to the fact that circulating levels are well below the level of detection.
Metabolism
Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolised, primarily in the liver.
Elimination
Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

5.3 Preclinical safety data
Carcinogenesis / Mutagenesis
Carcinogenesis
Long-term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate.
Genotoxicity
Clobetasol propionate was not mutagenic in a range of in vitro bacterial cell assays.
Reproductive Toxicology
Fertility
In fertility studies, subcutaneous administration of clobetasol propionate to rats at doses of 6.25 to 50 micrograms/kg/day produced no effects on mating, and fertility was only decreased at 50 micrograms/kg/day.
Pregnancy
Subcutaneous administration of clobetaol propionate to mice (≥100 micrograms/kg/day), rats (400 micrograms/kg/day) or rabbits (1 to 10 micrograms/kg/day) during pregnancy produced foetal abnormalities including cleft palate and intrauterine growth retardation.
In the rat study, where some animals were allowed to litter, developmental delay was observed in the F1 generation at ≥100 micrograms/kg/day and survival was reduced at 400 micrograms/kg/day. No treatment-related effects were observed in F1 reproductive performance or in the F2 generation.

6 Pharmaceutical particulars

6.1 List of excipients
Light liquid paraffin, Propylene Glycol, Hard paraffin Wax, Micro Crystalline Wax, Cetosteryl Alcohol, Benzyl Alcohol, Cetomacrogol 1000, Chlorocresol, Butylated Hydroxytoluene, Tartrazine Supra, LRL Lemon Flavour, Lemon Extract.

6.2 Incompatibilities
Not applicable

6.3 Shelf life
36 months

6.4 Special precautions for storage
- Store at temperature below 30° C.
- Do not freeze, Protect from direct sunlight.
- Keep all medicines out of the reach of children.
- Avoid contact with eyes.
- Keep the tube tightly close after use.

6.5 Nature and contents of container
Primary packing : 30 gm of cream filled in lami tube.
Secondary packing: Such one lami tube is packed in a carton along with leaflet.
Tertiary packing: 10 Cartons are packed in a shrink. Such 50 shrinks are packed in 5 ply shipper. Shippers to be sealed with BOPP tape.

6.6 Special precautions for disposal and other handling
None

7 Applicant / Manufacturer
Applicant

Applicant name and address	**M/s. PRIYA PHARMACEUTICAL NIG. LTD.** No. C-1, Airport Road, 2F, Kano State, Nigeria.
Contact person's phone number	
Contact person's email	

Manufacturer

Manufacturer name and address	**M/s. ASTAMED HEALTHCARE (I) PVT. LTD.** Plot No. 2 & 3, Phase II, Genesis Ind. Complex, Kolgaon, Dist. Thane, Tal. Palghar, 401404 Maharashtra State, India
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