

Centaur Pharmaceuticals Pvt. Ltd.

REGISTRATION DOSSIER		
Name of the Product	TASOL GM CREAM	Module-1 – Administrative Information

1.3.1 Package Insert /Summary of Product Characteristics (SmPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

Tasol – GM cream

1.1 Strength:

Clobetasol Propionate BP	0.05% w/w
Miconazole Nitrate BP	2% w/w
Gentamicin Sulphate BP equivalent to Gentamicin	0.1% w/w
Preservative:	
Chlorocresol BP	0.1% w/w
Cream base	

1.2 Pharmaceutical form:

Cream

QUALITATIVE AND QUANTITATIVE COMPOSITION:

1.3 Qualitative Declaration

Clobetasol Propionate BP	0.05% w/w
Miconazole Nitrate BP	2% w/w
Gentamicin Sulphate BP equivalent to Gentamicin	0.1% w/w
Preservative:	
Chlorocresol BP	0.1% w/w
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1.4 Quantitative Declaration

Name of Ingredients	Quantity in % w/w	Overages	Batch Qty in Kg
Clobetasol Propionate BP	0.05	2%	0.204
Miconazole Nitrate BP	2.0	—	8.0
Gentamicin sulphate BP	0.1	4%	0.705*
White soft Paraffin BP	5.0	—	20.0
Liquid liquid Paraffin BP	6.0	—	24.0
Cetostearyl alcohol BP	8.0	—	32.0
Cetomacrogol 1000 BP	2.0	—	8.0
Chlorocresol BP	0.1	—	0.4
Dibasic Potassium Phosphate BP	0.25	—	1.0
Disodium Edetate BP	0.01	—	0.04
Propylene Glycol BP	5.0	—	20.0

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2 PHARMACEUTICAL FORM:

Eye/Ear Drop

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Tasol – GM Cream is indicated in:

- ☐ Chronic dermatitis of the extremities
- ☐ Eczematoid dermatitis
- ☐ Follicular dermatitis
- ☐ Intertrigo
- ☐ Tinea pedis (athlete's foot)/

Photosensitive dermatitis

4.2 Posology and method of administration

Tasol – GM cream should be applied to cover completely the affected area twice daily.

4.3 Contraindications

Tasol – GM Cream is contraindicated in those patients with a history of sensitivity reactions to any of its components.

4.4 Special warnings and precautions for use

Tasol – Gm is meant for external use only.

Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal from treatment.

Patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression.

Manifestations of Cushing syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on therapy. Paediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

If irritation or sensitization develops with the use of Tasol – GM cream, treatment should be discontinued and appropriate therapy instituted. Prolonged use of topical antibiotics occasionally may result in overgrowth of non – susceptible organisms. If this occurs or if irritation, sensitization or super infection develops, treatment with Tasol – GM cream should be discontinued & appropriate therapy instituted

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4.5 Interaction with other medicinal products and other forms of interaction

There has been no serious effect or drug interactions reported among the active ingredient present in the cream.

4.6 Pregnancy and lactation

There are no adequate and well-controlled studies of the teratogenic potential of Tasol – GM in pregnant women. Tasol – GM cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

4.7 Effects on ability to drive and use machines

Not Applicable.

4.8 Undesirable effects

Rare side effects include: Thinning of the skin; the appearance of fine blood vessels on the skin surface; infection of hair follicles; excessive unwanted hair growth; redness & irritation around the mouth (perioral dermatitis); allergic skin reaction.

4.9 Overdose

Symptoms: Excessive or prolonged use of topical corticosteroids can suppress pituitary adrenal function, resulting in secondary adrenal insufficiency & produce manifestation of hypercorticism, including Cushing's disease.

Excessive or prolonged use of topical antibiotics may lead to overgrowth of lesions by nonsusceptible organisms.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Tasol-GM Cream is a combination of a topical steroid clobetasol propionate along with an antibacterial agent Gentamicin and antifungal agent Miconazole nitrate.

Clobetasol propionate has a potent glucocorticosteroid and weak mineralocorticosteroid activity. The mechanism for the anti-inflammatory action of clobetasol propionate is unknown. It is postulated that these steroids control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid.

Gentamicin acts on the bacteria by interfering with bacterial protein synthesis by binding to 30 S ribosomes. It has bactericidal action against many gram negative aerobes and against some strains of staphylococci.

Miconazole nitrate is a synthetic antifungal agent which inhibits the growth of the

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common dermatophytes, *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum*, the yeast-like fungus, *Candida albicans*. and the organism responsible for tinea versicolor. (*Malassezia furfur*). Miconazole damages fungal organisms by interfering with ergosterol biosynthesis, which results in toxic methylated sterol levels.

Many skin disorders caused by inflammation, fungal and bacterial attacks lead to itching and subsequent scratching, which among other causes, can in turn lead to serious and complicated secondary infections

Topical antibacterial and antifungal agents have profound efficacy in primary & secondary bacterial & fungal skin infections of varied etiology due to their antibacterial/antifungal properties. A drawback of the monotherapy with any topical antibacterial or antifungal has been the relatively slow onset of the anti-inflammatory effect compared to steroids.

Steroids provide much wanted rapid relief of the pruritus. Combining antibacterial & antifungal agents with topical corticosteroids in Tasol-GM is expected to provide fast relief because of the steroid effect and a lingering post treatment antibacterial & antifungal effect allowing for an overall reduction in clinical symptoms.

5.2 Pharmacokinetic properties

Studies in rabbits suggest that gentamicin is absorbed into the aqueous humor following topical application of the ophthalmic ointment or solution to the eye; no antibiotic was detected in the vitreous humor. Absorption of the drug is greatest when the cornea is abraded.

Gentamicin and other aminoglycosides are poorly absorbed from the gastro– intestinal tract but are rapidly absorbed after intramuscular injection. Average peak plasma concentrations of about 4 µg per mL have been obtained in patients with normal renal function 30 to 60 minutes after intramuscular administration of a dose equivalent to 1 mg of gentamicin per kg body-weight, which is similar to concentration achieved after intravenous infusion. There may be considerable individual variation. Several doses are required before equilibrium concentrations are obtained in the plasma and this may represent the saturation of binding sites in body tissues such as the kidney. Binding of gentamicin to plasma protein is usually low.

Following parenteral administration gentamicin and other aminoglycosides diffuse mainly into extracellular fluids. However, there is little diffusion into the cerebrospinal fluids and even when the meninges are inflamed effective concentrations may not be achieved; diffusion into the eye is also poor. Aminoglycosides diffuse readily into the perilymph of the inner ear. They cross the placenta but only small amounts have been reported in breast milk.

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5.3 Preclinical safety data**Chronic Toxicity:**

Preclinical data reveal no special hazard for humans based on conventional studies on safety, pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and reproductive toxicity.

6. PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

White soft paraffin BP, Light liquid paraffin BP, Cetostearyl alcohol BP, Cetomacrogol 1000 BP, Chlorocresol BP, Dibasic Potassium Phosphate BP, Edetate disodium BP, Propylene Glycol BP.

6.2 Incompatibilities

None.

6.3 Shelf life

24 months from the date of manufacture

6.4 Special precautions for storage

Store at temperature between 15-30 °C in a dark place. Do not freeze.

6.5 Nature and contents of container

10 g tube which in turn packed in well labelled cartons.

4.2 Special precautions for disposal and other handling:

Any unused product or waste material should be disposed of in accordance with local requirements.

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5. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS:

Marketing Authorization holder:

Centaur Pharmaceuticals Pvt. Ltd. Centaur House, Near Grand Hyatt, Shanti Nagar, Vakola, Santacruz (E), Mumbai 400 055, India

6. MARKETING AUTHORISATION NUMBER

528(41)/MFG/DFDA/2004/7017 dtd.17.11.2005

7. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

17/11/2005

8. DATE OF REVISION OF THE TEXT: Aug 2023

9. DOSIMETRY (IF APPLICABLE): NOT APPLICABLE.

10. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

NOT APPLICABLE.