	<p align="center">HAB PHARMACEUTICALS & RESEARCH LTD. 10, Pharmacy, Sidcul, Selaqui, Dehradun, Uttarakhand 248011</p>
<p>Product name</p>	<p align="center">TURBODERM (Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream)</p>

1.3.1 Summary of Product Characteristics (SmPC)

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

TURBODERM CREAM

(Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream)

2. Qualitative and quantitative composition

Beclomethasone Dipropionate USP.	0.025 % w/w
Clotrimazole BP	1 % w/w
Neomycin Sulphate USP	
Eq. to Neomycin	0.5 % w/w
Chlorocresol	0.1 % w/w
(As Preservative)	
In a Cream Base	q.s.

3. Pharmaceutical form

Cream

4. Clinical particulars

4.1 Therapeutic indications

Short-term topical treatment of tinea infections due to Trichophyton rubrum; T.mentagrophytes; Epidermophyton floccusum and Microsporum canis; candidiasis due to Candida albicans.

4.2 Posology and method of administration

Posology

Adults and children over the age of 12 years. Topical administration twice daily for two weeks (tinea cruris, tinea corporis and candidiasis) or for four weeks (tinea pedis).

Paediatric population

Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream is not recommended for children under the age of twelve years.

Method of administration

Topical administration only.

4.3 Contraindications



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Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream is contraindicated in those patients with a history of sensitivity to any of its components or to other corticosteroids or imidazoles.

If irritation or sensitisation develops with the use of Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream, treatment should be discontinued and appropriate therapy instituted.

Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream is contraindicated in facial rosacea, acne vulgaris, perioral dermatitis, napkin eruptions and bacterial or viral infections.

4.4 Special warnings and precautions for use

Local and systemic toxicity is common especially following long continued use on large areas of damaged skin and in flexures. If used on the face, courses should be limited to 5 days.

Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream should not be used with occlusive dressing.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following the development of tolerance, risk of generalised pustular psoriasis and local and systemic toxicity due to impaired barrier function of the skin.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, manifestation of Cushing's syndrome, hyperglycemia, and glycosuria may also occur with topical steroids, especially in infants and children.

Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream is not intended for ophthalmic use.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes of visual disturbances which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Paediatric population

- Long term continuous therapy should be avoided in all children irrespective of age.
 - Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream should not be used with adhesive dressing.
 - The safety and effectiveness of Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream has not been established in children below the age of 12.
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- If used on children, courses should be limited to 5 days.

Hypothalamic-pituitary adrenal axis suppression, Cushing's syndrome and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestation of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestation of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilloedema.

Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream contains:

Cetostearyl alcohol which may cause localised skin reactions (e.g. contact dermatitis).

Propylene glycol which may cause skin irritation. Because this medicine contains propylene glycol, do not use it on open wounds or large areas of broken or damaged skin (such as burns).

Benzyl alcohol which may cause allergic reactions or mild local irritation.

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is inadequate evidence of safety in pregnancy. Clotrimazole has shown no teratogenic effect in animals but is foetotoxic at high oral doses.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in human foetus. Hence Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream should only be used in pregnancy if the benefit justifies the potential risk to the foetus and such use should not be extensive i.e. in large amounts or for long periods.

4.7 Effects on ability to drive and use machines

Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions reported for Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream include: burning and stinging, maculopapular rash, oedema, paraesthesia and secondary infection.

Reported reactions to clotrimazole include erythema, stinging, blistering, peeling, oedema, pruritus, urticaria and general irritation of the skin.



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Reactions to betamethasone dipropionate include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hyperpigmentation, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae miliaria, capillary fragility (ecchymoses), blurred vision and sensitisation.

In children receiving topical corticosteroids, Hypothalamic-pituitary adrenal (HPA) axis suppression (HPA) axis suppression, Cushing's syndrome and intracranial hypertension have been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Acute overdosage with topical application of Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream is unlikely and would not be expected to lead to a life-threatening situation; however topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects.

Toxic effects are unlikely to occur following accidental ingestion of Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream . Signs of toxicology appearing after such accidental ingestion should be treated symptomatically.

5. Pharmacological properties

5.1 Pharmacodynamic properties


Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream contains the dipropionate ester of betamethasone, a glucocorticoid exhibiting the general properties of corticosteroids, and clotrimazole which is an imidazole antifungal agent.

Topical corticosteroids are effective in the treatment of a range of dermatoses because of their anti-inflammatory anti-pruritic and vasoconstrictive actions.

Clotrimazole is a broad-spectrum antifungal agent with activity against Trichomonas, Staphylococci and Bacteroides.

5.2 Pharmacokinetic properties

Clotrimazole, Beclomethasone Dipropionate, Neomycin Sulfate Cream is intended for treatment of skin conditions and is applied topically. Thus there are minimal pharmacokinetic aspects related to bioavailability at the site of action.

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Clotrimazole penetrates the epidermis after topical administration but there is little, if any, systemic absorption.

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of skin and use of occlusion.

Systemically absorbed topical corticosteroids are bound to plasma proteins metabolised in the liver and excreted by the kidneys. Some corticosteroids and their metabolites are also excreted in the bile.

6. Pharmaceutical particulars

6.1 List of excipients

- Cetomacrigol 1000
- Cetosearyl Alcohol
- White soft paraffine
- Light liquid paraffin
- Chorocresol
- Disodium edetate
- Propylene glycol
- Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 25° C..

6.5 Nature and contents of container

15 grams cream packed in collapsible Aluminium tubes embossed with batch number, manufacturing date and expiry dates packed in unit box with an insert.

7. Marketing Authorization Holder

HAB PHARMACEUTICAL & RESEARCH LTD.

10, Pharmacy, Sidcul, Selaqui, D
ehradun, Uttarakhand 248011

8. Marketing authorization number(s)

9. Date of first Authorization/Renewal of the Authorization:

