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CIN NO: U24231GJ1992PLC018237

BIOVIDERM - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

1.1. Name of the medicinal product:

Generic Name/INN Name: Beclomethasone Dipropionate, Neomycin Sulphate and Miconazole

Trade Name: BIOVIDERM

1.2 Strength:

Beclomethasone Dipropionate BP	0.25 mg
Neomycin Sulphate BP Eq. to Neomycin base	5.00 mg
Miconazole Nitrate BP	20.00 mg
Cholorocresol BP	0.1 %
(As Preservative)	

1.3 Pharmaceutical form: Cream (For External use only)

2. Qualitative and Quantitative composition:

Sr. No.	Ingredients	Specification	Qty (mg/ gm)	Actual qty. per/ Tube (mg)	% w/w	Function
1.	Beclomethasone Dipropionate	BP 2018	0.25	8.34	0.03	Active ingredient
2.	Neomycin Sulphate eq. to Neomycin base	BP 2018	5.00	189.54	0.63	Active ingredient
3.	Miconazole Nitrate	BP 2018	20.00	634.26	2.11	Active ingredient
4.	Chlorocresol	BP 2018	1.00	30.00	0.10	Preservative
5.	Light Liquid Paraffin	BP 2018	72.00	2160.00	7.20	Humectant
6.	Cetostearyl Alcohol	BP 2018	50.11	1503.30	5.01	Emulsifying agent
7.	Cetomacrogol 1000	IH	14.31	429.30	1.43	Emollient
8.	White Petroleum Jelly	BP 2018	114.60	3438.00	11.46	Moisturizing agent
9.	Propylene Glycol	BP 2018	43.00	1290.00	4.30	Humectant
10	Flav. fern lavandar-P5167	IH	0.30	9.00	0.03	Flavoring agent
11.	Purified Water BP	BP 2018	q. s. to make 1.00 gm	q. s. to make 30.00 gm	Up to 100.00 % w/w	Vehicle

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3. Pharmaceutical form:

Dosage Form: Cream (For External use only)

Visual & Physical characteristics of the product

A white coloured homogeneous semisolid mass.

4. Clinical particulars:

4.1. Therapeutic indications:

Beclomethasone Dipropionate, Neomycin Sulphate and Miconazole cream is a synthetic chlorinated corticosteroid. It is active topically and produces a rapid and sustained response in eczema and dermatitis of all types, including atopic eczema, photodermatitis, lichen planus, lichen simplex, prurigo nodularis, discoid lupus erythematosus, necrobiosis lipoidica, pretibial myxodemea and erythroderma. It is also effective in the less responsive conditions such as psoriasis of the scalp and chronic plaque psoriasis of the hands and feet, but excluding widespread plaque psoriasis, used as a cream to prevent and treat bacterial infections of the skin, for the treatment of mycotic infections of the skin and nails and superinfections due to Gram-positive bacteria.

4.2. Posology and method of administration:

Route of administration:

Cutaneous use.

Adults and Children:

Fungal infections of the skin: Once to twice daily. In most cases a thin film of Beclomethasone Dipropionate, Neomycin Sulphate and Miconazole Cream should be applied to cover the affected area twice daily. For some patients adequate maintenance therapy may be achieved with less frequent application.

Beclomethasone Dipropionate, Neomycin Sulphate and Miconazole Cream is especially appropriate for moist or weeping surfaces and the ointment for dry, lichenifield or scaly lesions but this is not invariably so.

The duration of therapy varies from 2 to 6 weeks depending on the localisation and the severity of the lesion. Treatment should be continued at least one week after disappearance of all signs and symptoms.

Nail infections: Apply the cream once or twice daily to the lesions. Treatment should be prolonged for 10 days after all lesions have disappeared to prevent relapse.

4.3. Contraindications:

Rosacea, acne, perioral dermatitis, perianal and genital pruritus. Hypersensitivity to any of the ingredients of the Beclomethasone Dipropionate, Neomycin Sulphate and Miconazole cream presentations contra-indicates their use as does tuberculous and most viral lesions of the skin, particularly herpes simplex, vacinia, varicella. Beclomethasone Dipropionate, Neomycin Sulphate and Miconazole cream should not be used in napkin eruptions, fungal or bacterial skin infections without suitable concomitant anti-infective therapy.

4.4 Special warnings and precautions for use:

Local and systemic toxicity is common, especially following long continuous use on large areas of damaged skin, in flexures or with polythene occlusion. If used in children or on the face courses should be limited to 5 days. Long term continuous therapy should be avoided in all patients irrespective of age.

Occlusion must not be used.

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

General: Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome also can be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

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Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

Paediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

If irritation develops, treatment should be discontinued and appropriate therapy instituted.

Paediatric population:

Paebaediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and to exogenous corticosteroid-induced HPA axis suppression and to exogenous corticosteroid effects than adult patients because of greater absorption due to a larger skin surface area to body weight ratio. HPA axis suppression, Cushing's syndrome and intracranial hypertension have been reported in paediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in paediatric patients include linear growth retardation, delayed weight gain, low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilledema.

Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported during treatment with Beclomethasone Dipropionate, Neomycin Sulphate and Miconazole cream and with other miconazole topical formulations. If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued. Beclomethasone Dipropionate, Neomycin Sulphate and Miconazole cream must not come into contact with the mucosa of the eyes.

Benzoic acid is mildly irritant to the skin, eyes and mucous membranes.

Butylated hydroxyanisole may cause local skin reactions (e.g.contact dermatitis), or irritation to the eyes and mucous membranes.

4.5 Interaction with other medicinal products and other forms of interaction:

Miconazole administered systemically is known to inhibit CYP3A4/2C9. Due to the limited systemic availability after topical application, clinically relevant interactions are rare. However, in patients on oral anticoagulants, such as warfarin, caution should be exercised and anticoagulant effect should be monitored.

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