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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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4.6 Pregnancy and lactation:

There are no adequate and well controlled studies of the teratogenic potential of topically applied corticosteroids in pregnant women. Therefore topical steroids should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

In animals miconazole nitrate has shown no teratogenic effects but is foetotoxic at high oral doses. Only small amounts of miconazole nitrate are absorbed following topical administration. However, as with other imidazoles, miconazole nitrate should be used with caution during pregnancy.

Lactation

It is not known whether topical administration of corticosteroids would result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, a decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother.

Topically applied miconazole is minimally absorbed into the systemic circulation, and it is not known whether miconazole is excreted in human breast milk. Caution should be exercised when using topically applied miconazole products during lactation.

4.7. Effects on ability to drive and use machines:

Not applicable.

4.8 Undesirable effects:

Beclomethasone Dipropionate, Neomycin Sulphate and Miconazole skin preparations are generally well tolerated and side-effects are rare. The systemic absorption of beclomethasone dipropionate may be increased if extensive body surface areas or skin folds are treated for prolonged periods or with excessive amounts of steroids. Suitable precautions should be taken in these circumstances, particularly with infants and children.

The following local adverse reactions that have been reported with the use of Beclomethasone Dipropionate, Neomycin Sulphate and Miconazole include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria.

Continuous application without interruption may result in local atrophy of the skin, striae and superficial vascular dilation, particularly on the face.

System Organ Class	Adverse Reactions	
	Frequency Category	
	Uncommon (≥1/1,000 to <1/100)	Not Known
Immune System Disorders		Anaphylactic reaction Hypersensitivity
Skin and Subcutaneous Tissue Disorders	Skin burning sensation Skin inflammation	Angioedema Urticaria Contact dermatitis Rash Erythema Pruritus
General Disorders and Administration Site Conditions	Application site reactions (including application site irritation, burning, pruritus, reaction NOS and warmth)	

4.9. Overdose:

Symptoms

Cutaneous use: Excessive use can result in skin irritation, which usually disappears after discontinuation of therapy.

Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal functions resulting in secondary adrenal insufficiency which is usually reversible.

Accidental ingestion: Stomach irritation may occur.

Treatment

Beclomethasone Dipropionate, Neomycin Sulphate and Miconazole cream is intended for cutaneous use, not for oral use. If accidental ingestion of large quantities of the product occurs, use appropriate supportive care.

In such cases appropriate symptomatic treatment is indicated. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, reduce the frequency of application, or to substitute a less potent steroid.

The steroid content of each tube is so low as to have little or no toxic effect in the unlikely event of accidental oral ingestion

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5. Pharmacological properties:

5.1 Pharmacodynamic properties:

Beclomethasone Dipropionate, Neomycin Sulphate and Miconazole cream preparations contain the dipropionate ester of betamethasone which is a glucocorticoid exhibiting the general properties of corticosteroids.

In pharmacological doses, corticosteroids are used primarily for their anti-inflammatory and/or immune suppressive effects.

Topical corticosteroids such as beclomethasone dipropionate are effective in the treatment of a range of dermatoses because of their anti-inflammatory, anti-pruritic and vasoconstrictive actions. However, while the physiologic, pharmacologic and clinical effects of the corticosteroids are well known, the exact mechanisms of their action in each disease are uncertain.

Neomycin is bactericidal; it binds directly to the 30S ribosomal subunit, thus inhibiting bacterial protein synthesis. Its spectrum of action includes many aerobic gram-negative organisms and some aerobic gram-positive organisms. Drug is far less active against many gram-negative organisms than are amikacin, gentamicin, netilmicin, and tobramycin. Given orally or as retention enema, neomycin inhibits ammonia-forming bacteria in the GI tract, reducing ammonia and improving neurologic status of patients with hepatic encephalopathy. It's rarely given systemically because of its high potential for ototoxicity and nephrotoxicity.

Miconazole nitrate:

Pharmacotherapeutic classification: (Antifungals for dermatological/topical use; imidazole derivative) ATC code: D01A C02.

Miconazole nitrate is an imidazole antifungal agent and may act by interfering with the permeability of the fungal cell membrane. It possesses a wide antifungal spectrum and has some antibacterial activity.

5.2 Pharmacokinetic properties:

Beclomethasone dipropionate:

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of the epidermal barrier and the use of occlusive dressings.

Topical corticosteroids can be absorbed through intact, normal skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Once absorbed through the skin, topical corticosteroids enter pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees, are metabolised primarily in the liver and excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted in the bile.

Neomycin sulphate:

Neomycin isn't absorbed through intact skin; it may be absorbed from wounds, burns, or skin ulcers.

Metabolism: Not metabolized.

Miconazole nitrate:

Absorption: There is little absorption through skin or mucous membranes when miconazole nitrate is applied topically.

Distribution: Absorbed miconazole is bound to plasma proteins (88.2%) and red blood cells (10.6%).

Metabolism and Excretion: The small amount of miconazole that is absorbed is eliminated predominantly in faeces as both unchanged drug and metabolites.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of local irritation, single and repeated dose toxicity, genotoxicity, and toxicity to reproduction

6. Pharmaceutical particulars:

6.1. List of Excipients:

The list of excipients is as follows:

Chlorocresol

Light Liquid Paraffin

Cetostearyl Alcohol

Cetomacrogol 1000

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White Petroleum Jelly

Propylene Glycol

Flav. fern lavandar-P5167

Purified Water

6.2 Incompatibilities:

Not applicable

6.3. Shelf life:

36 months

6.4. Special precautions for storage:

Store away from light.and in cool dry place

6.5. Nature and contents of container:

One lamitube of 30 g is pack in printed carton of Bioviderm Cream with Patient information leaflet.

6.6. Special precautions for disposal:

No special requirement.

7. Applicant

Name and Address of Applicant

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