



YASH MEDICARE PVT. LTD.

PHILOBACT

Clotrimazole, Betamethasone Dipropionate, and Neomycin Sulfate Cream

1.3 Product Information

1.3.1 Summary of product characteristics (SmPC)

1.3.1.1 Name of the medicinal product: PHILOBACT (Clotrimazole, Betamethasone Dipropionate, and Neomycin Sulfate Cream)

1.3.1.2 Qualitative and quantitative composition:

Sr. No.	Ingredients	Specification	Label Claim / gm (in % w/w)	Over-ages (in %)	Qty. in gm per kg of product	Reason for inclusion
1	Betamethasone Dipropionate eq. to Betamethasone	USP	0.05%	5%	0.675	Active
2	Clotrimazole	USP	1.0%	5%	10.500	Active
3	Neomycin Sulfate	USP	0.5%	25%	6.250	Active
4	White Soft paraffin	BP	---	---	150.000	Moisturiser
5	Cetostearyl Alcohol	BP	---	---	72.000	Opacifying Agent
6	Cetomacrogol 1000	BP	---	---	18.000	Solubilizer & Emulsifying Agent
7	Light Liquid Paraffin	BP	---	---	35.000	Emollient
8	Chlorocresol	USP	0.1%	---	1.000	Preservative
9	Propylene Glycol	BP	---	---	40.000	Solvent
10	Purified Water	BP	---	---	q.s.	Vehicle

1.3.1.3 Pharmaceutical form: Semi solid external preparation

1.3.1.4 Clinical Particulars

1.3.1.4.1 Therapeutic indications

PHILOBACT CREAM is indicated for topical use in the treatment of a wide range of eczemas and other inflammatory and allergic infections of the skin caused by various bacteria / fungi. This condition includes contact dermatitis, follicular dermatitis, impetigo, intertrigo, eczematoid dermatitis, non specific pruritus etc.

1.3.1.4.2 Posology and method of administration

After cleaning the affected area, a sufficient quantity of **PHILOBACT CREAM** should be applied to the affected area to form a thin even layer, two or three times daily. This treatment should be continued for several days after the disappearance of symptoms.

1.3.1.4.3 Contraindications

PHILOBACT CREAM is contraindicated:

- if you are allergic to betamethasone dipropionate, clotrimazole and neomycin sulfate or any of the other ingredients of this medicine.



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- if your skin becomes irritated, or you develop an allergic reaction.
- do not use on any other skin infections as it could make them worse, especially rosacea (a skin condition affecting the face), acne, dermatitis (skin inflammation) around the mouth, nappy rash or other skin infections.

1.3.1.4.4 Special warnings and precautions for use

If you have psoriasis, your doctor may want to review your treatment regularly. Contact your doctor if your psoriasis gets worse or you get raised bumps filled with pus under your skin.

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

Side effects that may happen with inhaled or oral corticosteroids may also occur with corticosteroids used on the skin, especially in infants and children.

If you use more than the correct amount of cream and/or use it for longer than is recommended, it can affect the levels of certain hormones in the body, particularly in infants and children.

In adults the changes in hormone levels may lead rarely to puffiness or rounding of the face, weakness, tiredness, and dizziness when standing or sitting down.

Children

Do not use this medicine on children under 12 years of age unless advised by your doctor.

If you use more than the correct amount of cream and/or use it for longer than is recommended, it can affect your child's hormones. Rarely this may lead to:

- Delayed growth and development
- A moon face or rounding of the face
- A build-up of pressure around the brain which can produce
 - a bulging of the fontanelle (the soft spot in the top of the skull) in infants
 - a constant thumping headache
 - blurred vision or other visual disturbances

1.3.1.4.5 Interaction with other medicinal products and other forms of interaction

Following significant systemic absorption, Neomycin Sulfate can intensify and prolong the respiratory depressant effects of neuromuscular blocking agents.

Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives. Consequently the effectiveness of such contraceptives may be reduced. Patients should be advised to use alternative precautions for at least five days after using this product.

1.3.1.4.6 Pregnancy and Lactation

There is little information to demonstrate the possible effect of topically applied Neomycin in pregnancy and lactation. However, Neomycin present in maternal blood can cross the placenta and may give rise to a theoretical risk of foetal toxicity, thus use of this medicinal product is not recommended in pregnancy or lactation.

Pregnancy:

There is a limited amount of data from the use of clotrimazole in pregnant women. Animal studies with clotrimazole have shown reproductive toxicity at high oral doses. At the low systemic exposures of clotrimazole following topical treatment, harmful effects with respect to reproductive toxicity are not predicted. Clotrimazole can be used during pregnancy but only under the supervision of a physician or midwife.



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Lactation:

Available pharmacodynamic/toxicological data in animals have shown excretion of clotrimazole/metabolites in milk after intravenous administration. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from clotrimazole therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility:

No human studies of the effects of clotrimazole on fertility have been performed; however, animal studies have not demonstrated any effects of the drug on fertility.

1.3.1.4.7 Effects on ability to drive and use machines

Not applicable.

1.3.1.4.8 Undesirable effects

Skin atrophy or striae may occur following long-term treatment with preparation containing corticosteroids.

1.3.1.4.9 Overdose

Acute overdosage with topical application of **PHILOBACT 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 **PHILOBACT CREAM**. Signs of toxicology appearing after such accidental ingestion should be treated symptomatically.

1.3.1.5 Pharmacological properties

1.3.1.5.1 Pharmacodynamic properties

PHILOBACT CREAM contains the dipropionate ester of betamethasone, a glucocorticoid exhibiting the general properties of corticosteroids, clotrimazole which is an imidazole antifungal agent and Neomycin Sulfate which is aminoglycoside antibiotics.

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.

Neomycin mediates its bactericidal action by inhibiting bacterial protein synthesis, thereby suppressing the growth and survival of susceptible bacteria.

1.3.1.5.2 Pharmacokinetic properties

Clotrimazole

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



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Betamethasone Dipropionate

The absorption and potency of any topical corticosteroid including betamethasone depends on the vehicle in which the steroid is delivered. The metabolism of betamethasone yields 6 metabolites. The metabolic processes include 6 β hydroxylation, 11 β -hydroxyl oxidation, and reduction of the C-20 carbonyl group followed by removal of the side chain. Corticosteroids are eliminated predominantly in the urine.

Neomycin Sulfate

The small absorbed fraction is rapidly distributed in the tissues and excreted by the kidneys. The unabsorbed portion of neomycin (97%) is primarily excreted unchanged in feces. The amount of systemically absorbed neomycin transferred to the tissues increases cumulatively with repeated dosing with the kidneys as the primary excretory path. With repeated dosing, progressive accumulation also occurs in the inner ear. Release of tissue-bound neomycin occurs slowly over a period of several weeks after dosing has been discontinued. Protein binding is low (0—30%).

1.3.1.5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of this SmPC.

1.3.1.6 Pharmaceutical particulars

1.3.1.6.1 List of excipients

White Soft paraffin, Cetostearyl Alcohol, Cetomacrogol 1000, Light Liquid Paraffin, Chlorocresol, Propylene Glycol, Purified Water.

1.3.1.6.2 Incompatibilities

Not applicable

1.3.1.6.3 Shelf life

36 months

1.3.1.6.4 Special precautions for storage

Store below 25°C. Protected from light. Do not allow to freeze.
Keep all medicines out of reach of children.

1.3.1.6.5 Nature and contents of container

Primary packing: 30 gm of Cream is filled in a Lamitube.

Secondary packing: Such 1 tube is packed an inner carton along with leaflet.

Tertiary packing: 12 Inner cartons are packed in an outer carton. Individually shrink outer carton. Such 30 Shrinks are packed in a 5 Ply Shipper sealed with BOPP tape & strap with strapping roll.

1.3.1.6.6 Special precautions for disposal and other handling

None.