SUMMARY OF PRODUCT CHARACTERISTICS

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1. NAME OF THE MEDICINAL PRODUCT

Funbact A Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION Each gm contains:

Clotrimazole USP	1.0 % w/w
Betamethasone Dipropionate USP equivalent to Betamethasone	0.05 % w/w
Neomycin sulphate USP	0.5 % w/w Cream
base	q.s. Chlorocresol USP/NF 0.1 % w/w

3. PHARMACEUTICAL FORM

Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

FUNBACT-A provides a comprehensive treatment for various inflammatory dermatological disorders superadded with bacterial or superficial fungal infections of the skin. Betamethasone Dipropionate is one of the most potent topical corticosteroid available and rapidly controls the symptoms such as itching, redness and scaling.

Many times the inflammatory skin disorders which respond to topical corticosteroids are superadded with bacterial and/or fungal infections of the skin. In these condtions, treatment with anti - inflammatory agents alone is not sufficient and a proper antibiotic has to be added in the regimen. Clotrimazole s a broad spectrum synthetic antifungal agent which has fungicidal action against all the fungi responsible for superficial fungal infections of the skin. Neomycin Sulphate is a broad spectrum antibacterial antibiotic. Hence FUNBACT-A Cream

effectively controls inflammatory disorders superadded with bacterial and/or fungal infections of the skin.

4.2 Posology and method of administration

Funbact-A should be thinly and evenly applied to the affected area two to three time a day with gentle rub. To be used only under medical supervision.

4.3 Contraindications

Hypersensitivity to Clotrimazole, Neomycin Sulphate and Betamethasone Dipropionate.

4.4 Special warnings and special precautions for use

Long-term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppression, with or without clinical features of Cushing's syndrome, can occur even without occlusion. In this situation, topical steroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency. If infection persists, systemic chemotherapy is required. Withdraw topical corticosteroid if there is a spread of infection.

Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings. and the skin should be cleansed before a fresh dressing is applied. Extended or recurrent application may increase the risk of contact sensitisation. Extension of infection may occur due to the masking effect of the steroid. Following significant systemic absorption, aminoglycosides such as neomycin can cause Irreversible ototoxicity; and neomycin has nephrotoxic potential. In renal impairment the plasma clearance of neomycin is reduced.

4.5 Interaction with other FPP's and other forms of interaction

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 5 days after using the product. Following significant systemic absorption. neomycin sulfate can intensify and prolong the respiratory depressant effects of neuromuscular blocking agents.

4.6 Pregnancy and lactation

Clotrimazole can be used during pregnancy, but only under the supervision of a physician.

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. To date, no other relevant epidemiological data are available. There are no adequate and well controlled studies of the teratogenic potential of topically applied Betamethasone dipropionate in pregnant women. Therefore FUNBACT-A should be used during pregnancy only If the potential benefit justifies the potential risk to the foetus.

Breast-feeding

It is unknown whether it is excreted in breast milk, so it should be given with caution to lactating mothers.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

There are reports of local skin irritation, burning, pruritus, pigmentation changes, allergic contact dermatitis and hypertrichosis with topical steroids. FUNBACT-A Cream preparation is usually well tolerated, but if signs of hypersensitivity appear, application should be stopped immediately. Side effects includes some of the Immune system disorders: allergic reaction (syncope, hypotension, dyspnoea, urticaria) Skin and subcutaneous tissue disorders: blisters, discomfort/pain, oedema, irritation, peeling/exfoliation, pruritus, rash, stinging/burning.

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 EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

Acute overdosage is very unlikely to occur. However, in the case of chronic overdosage or misuse the features of Cushing's syndrome may appear and in this situation topical steroids should be discontinued gradually under medical supervision.

Also, consideration should be given to significant systemic absorption of neomycin sulphate. If this is suspected, use of the product should be stopped and the patient's general status, hearing acuity, renal and neuromuscular functions should be monitored.

Blood levels of neomycin sulfate should also be determined. Haemodialysis may reduce the serum level of neomycin sulfate. In the event of accidental oral ingestion, gastric lavage is rarely required and should be considered only if a life-threatening amount of Clotrimazole has been ingested within the preceding hour or if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). It should be carried out only if the airway can be protected adequately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Betamethasone dipropionate can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of Betamethasone dipropionate. Once absorbed through the skin, Betamethasone dipropionate is handled through pharmacokinetic pathways similar to systematically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolised primarily by the liver and are then excreted by the kidneys. Neomycin is either not absorbed or is absorbed only minimally through intact skin. Any neomycin which is absorbed will be rapidly excreted by the kidneys in an unchanged state.

Pharmacokinetic investigations after dermal application have shown that clotrimazole is minimally absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.001 mcg/ml, suggesting that clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

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5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80 (Tween – 80) BP, Sodium Acid Phosphate dihydrate BP, Propylene Glycol BP, Parachloro Meta Cresol USP, Light Liquid Paraffin BP, Macrogol Cetostearyl Ether (N=22) C.M. – 1000, Cetostearyl Alcohol BP, Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

36 Months.

6.4 Special precautions for storage

Keep in cool & dry place. Store below 30°C. Do not Freeze.

6.5 Nature and contents of container

30 gm tube packed in carton along with an insert.

6.6 Instructions for use and handling

Do not dilute

7. MARKETING AUTHORISATION HOLDER Bliss
GVS Pharma Ltd.,
102, Hyde Park, Saki Vihar Road,
Andheri (East), Mumbai - 400 072.

8. Number(S) In the national register of finished pharmaceutical products registration no.
Certificate No: 05364/07926/NMR/2019

9. Date of first authorisation/renewal of the authorisation date when registered
Sep 29, 2020

10. Date of revision of the text

September 2023