SUMMARY OF PRODUCT CHARACTERISTICS
Funbact A Cream

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
   Aqueous Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Funbact A Cream is indicated for the treatment of the following conditions where secondary bacterial infection is present, suspected, or likely to occur

Adults and children (aged 2 years and over): Eczema including atopic and discoid eczemas; prurigo nodularis; psoriasis (excluding widespread plaque psoriasis); neurodermatoses including lichen simplex and lichen planus; seborrhoeic dermatitis; contact sensitivity reactions; insect bite reactions and anal and genital intertrigo.

4.2 Posology and method of administration

For topical administration.

Treatment should not be continued for more than 7 days without medical supervision.

Adults and children aged 2 years and over:

A small quantity should be applied to the affected area two or three times daily until improvement occurs. It may then be possible to maintain improvement by applying once a day or even less often.

When used in children, courses should be limited to 5 days, if possible.

Dosage in renal impairment:

Dosage should be reduced in patients with reduced renal function.

Elderly:

Funbact A cream are suitable for use in the elderly. Caution should be exercised in cases where a decrease in renal function exists and significant systemic absorption of neomycin sulphate may occur.

4.3 Contraindications:

Funbact A cream is contraindicated in patients with conditions such as rosacea, acne vulgaris, perioral dermatitis, perianal and genital pruritus, primary cutaneous viral infections, otitis externa and hypersensitivity to any component of the preparation.

Due to the known ototoxic and nephrotoxic potential of neomycin sulphate, use in large quantities or on large areas for prolonged periods of time is not recommended in circumstances where significant systemic absorption may occur.

4.4 Special warnings and 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. 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.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important. 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 medicinal products and other forms of interaction

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

4.6 Fertility, pregnancy and lactation

There is little information to demonstrate the possible effect of topically applied betametasone, neomycin and clotrimazole 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.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Prolonged and intensive treatment with highly active corticosteroid preparations may cause local atrophic changes in the skin such as thinning, striae, and dilatation of the superficial blood vessels, particularly when occlusive dressings are used or when skin folds are involved.

In rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease.

There are reports of local skin burning, pruritus, pigmentation changes, allergic contact dermatitis and hypertrichosis with topical steroids.

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Betamethasone is an active corticosteroid which produces a rapid response in those inflammatory dermatoses that are normally responsive to topical corticosteroid therapy, and is often effective in the less responsive conditions such as psoriasis.

Neomycin sulphate is a broad spectrum, bactericidal antibiotic effective against the majority of bacteria commonly associated with skin infections.

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane.

5.2 Pharmacokinetic properties

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

Once absorbed through the skin, topical corticosteroids are 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.

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.

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
Store in dry place, below 30°C.

6.5 Nature and contents of container
A white soft cream in packed in printed Aluminium collapsible Tubes with rubber latex and sealed nozzle with white Piercing cap.
One filled 30 gm Aluminium Tube insert in a printed mono carton along with leaflet.

6.6 Special precautions for disposal
Do not dilute

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

8. DATE OF REVISION OF THE TEXT
13/09/2019