SUMMARY OF PRODUCT CHARACTERISTIC

FUNTAG
(Betamethasone Dipropionate, Gentamicin, Tolnaftate &
Iodochlorhydroxyquinoline Lotion)

1. Name of the medicinal product

FUNTAG

2. Qualitative and quantitative composition

Each ml contains

Betamethasone Dipropionate USP…….. 0.643 mg

Gentamicin Sulfate BP equivalent to Gentamicin base……. 1 mg

Tolnaftate USP…… 10 mg

Iodochlorhydroxyquinoline……. 10 mg

Excipients ……..Q.S.

Chlorocresol BP……1 mg

3. Pharmaceutical form

Lotion

4. Clinical particulars

4.1 Therapeutic indications

FUNTAG Lotion is used for the short-term treatment of inflammatory skin conditions caused by bacterial or fungal infection.

4.2 Posology and method of administration

Adults and children above 2 years

A few drops of FUNTAG Lotion should be applied to the affected areas twice daily and massaged gently and thoroughly into the affected area. For some patient's adequate maintenance therapy may be achieved with less frequent application.

4.3 Contraindications

- FUNTAG Lotion are contraindicated in patients with hypersensitivity to any of the ingredients of the product
- Fungal or viral infections of the eyes or ears, tuberculosis infection affecting the eye, inflammation of the front of the eye (cornea) or the membrane lining the

eye (conjunctiva) due to the herpes simplex virus (herpetic keratitis), glaucoma, perforated eardrum and allergic reaction due to the product

- Rosacea, acne, perioral dermatitis, perianal and genital pruritus

4.4 Special warnings and precautions for use

- Not for injection or ingestion
- 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.
- Topical corticosteroids may be hazardous in psoriasis therefore caution is required
- 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
- 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
- The use of topical antibiotics occasionally allows overgrowth of nonsusceptible organisms, including fungi

4.5 Interaction with other medicinal products and other forms of interaction

- Aminoglycoside antibiotics given by injection may cause may have additive side effects

4.6. Fertility, pregnancy and lactation

- Should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus
- A decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother

4.7 Effects on ability to drive and use machines

None stated

4.8 Undesirable effects

The reported adverse effects are burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, and allergic contact dermatitis, maceration of the skin, photosensitization, 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.

4.9 Overdose

Betamethasone

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

5. Pharmacological properties

5.1 Pharmacodynamic properties

Betamethasone

Betamethasone, a corticosteroid is used for reducing inflammation. Neomycin is an aminoglycoside antibiotic which helps to prevent infections with bacteria. Corticosteroids work by acting within cells to decrease the release of substances that produce inflammatory reactions in a particular area, thereby reducing swelling, redness and itch.

Gentamicin

Gentamicin sulfate is a wide spectrum antibiotic that provides highly effective topical treatment in primary and secondary bacterial infections of the skin. Gentamicin Sulfate Cream may clear infections that have not responded to treatment with other topical antibiotic agents.

Tolnaftate

Tolnaftate is a well-established drug substance having potent antifungal properties.

Iodochlorhydroxyquinoline

Iodochlorhydroxyquinoline is a broad-spectrum antibacterial with antifungal properties. Application of Iodochlorhydroxyquinoline to extensive or eroded areas of the skin may lead to increased protein-bound iodine (PBI) levels within 1 week. In addition, elevated PBI levels may occur when relatively small areas of the skin are treated with Iodochlorhydroxyquinoline for more than 1 week. Iodochlorhydroxyquinoline is bacteriostatic, however, the precise mechanism of its action is unknown

5.2 Pharmacokinetic properties

Betamethasone

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.

Gentamicin

Topical gentamicin is readily absorbed from large burned, denuded, or granulating areas but not through intact skin. Absorption of gentamicin is faster and greater with the cream compared to the ointment.

Tolnaftate

Not applicable

Iodochlorhydroxyquinoline

Topical absorption is rapid and extensive, especially when the skin is covered with an occlusive dressing or if the medication is applied to extensive or eroded areas of the skin. Iodochlorhydroxyquinoline is absorbed through the skin in sufficient amounts to affect thyroid function tests.

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 the SPC.

6. Pharmaceutical particulars

6.1 List of excipients

Cetomacrogol 1000, Cetostearyl Alcohol BP, White Soft Paraffin BP, Chlorocresol USP, Propylene Glycol, Disodium Hydrogen Phosphate BP, Liquid paraffin, Sodium Metabisulphite BP, Sodium Dihydrogen phosphate dihydrate BP, Purified Water BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 Months

6.4 Special precautions for storage

Keep out of the reach and sight of children.

Do not use FUNTAG Lotion after the expiry date which is stated on the pack after Expiry.

The expiry date refers to the last day of that Month. Do not store above 30^{o}C. Store this Lotion in the original package.

6.5 Nature and contents of container:

30 ml Lotion filled in a Golden Pearlised Colour HDPE Dropper Bottle natural colour LDPE nozzle & HDPE pilfer proof spike Cap.

6.6 Special precautions for disposal and other handing.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

7. Marketing Authorization Holder:

Name: BLISS GVS PHARMA LTD.

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8. Marketing Authorization Numbers:

Not Applicable

9. Date of revision of first authorization/ renewal of authorization:

Not Applicable

10 Date of revision of text:

Not Applicable