DGF Drugfield **PHARMACEUTICALS LIMITED**

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

Betamethasone Cream

(Betamethasone Valerate 0.1%$^{W}/_{W}$)

1. NAME OF THE MEDICINALPRODUCT

Betamethasone (Betamethasone Valerate0.1%$^{W}/_{W}$) Cream

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each ml contains pentazocine base 3omg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream (semi-solid)

4. Clinical particulars

4.1 Therapeutic indications

Betamethasone Cream contains an active topical corticosteroid which produces a rapid response in those severe inflammatory skin disorders such as eczema, psoria .This medication is used to treat a variety of skin conditions (e.g., eczema, dermatitis, allergies, rash). Betamethasone reduces the swelling, itching, and redness that can occur in these types of conditions. This medication is a medium-strength corticosteroidsis, neurodermatoses, seborrheic dermatitis eczema, intertrigo, and non specific prupritis.

4.2 Posology and method of administration

Posology

Important Dosage and Administration Instructions

Use this medication on the skin only. However, do not use it on the face, groin, or underarms unless directed to do so by your doctor.

Wash and dry your hands before using. Clean and dry the affected area. Apply a thin film of medication to the affected area and gently rub in, usually 1-3 times daily or as directed by your doctor. Do not bandage, cover, or wrap the area unless directed to do so by your doctor. If used in the diaper area on an infant, do not use tight-fitting diapers or plastic pants.

After applying the medication, wash your hands unless you are using this medication to treat the hands. When applying this medication near the eyes, avoid getting it in the eyes because this may worsen or cause glaucoma. Also, avoid getting this medication in the nose or mouth. If you get the medication in these areas, rinse with plenty of water.

Use this medication only for the condition for which it was prescribed. Do not use it for longer than prescribed.

Inform your doctor if your condition persists or worsens after 2 weeks.

Initial Dosage

Apply a thin film topically to the affected area 1 or 2 times a day

Method of administration

Topical administration

4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients in the excipients listed in section 6.1.
The following conditions should not be treated with betamethasone valerate:
• Untreated cutaneous infections

- Rosacea
- Acne vulgaris
- Pruritus without inflammation
- Perianal and genital pruritus
- Perioral dermatitis

Betamethasone valerate is contraindicated in dermatoses in infants under one year of age, including dermatitis.

4.4 Special warnings and precautions foruse

Before using betamethasone, tell your doctor or pharmacist if you are allergic to it; or to other corticosteroids (e.g., hydrocortisone, prednisone); or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: poor blood circulation, diabetes, immune system problems.

Do not use if there is an infection or sore in the area to be treated.

Rarely, using corticosteroid medications for a long time or over large areas of skin can make it more difficult for your body to respond to physical stress. Therefore, before having surgery or emergency treatment, or if you get a serious illness/injury, tell your doctor or dentist that you are using this medication or have used this medication within the past few months.

4.5 Interaction with other medicinal products and other forms of interaction

Betamethasone interacts with the following drugs:
Fish oil,Vitamin B12, Vitamin C, Vitamin D3, Diphenhydramine.

4.6 Pregnancy and Lactation

Pregnancy

There are limited data from the use of betamethasone valerate in pregnant women.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development.

The relevance of this finding to humans has not been established; however, administration of betamethasone valerate during pregnancy should only be considered if the expected benefit to the mother outweighs the risk to the foetus. The minimum quantity should be used for the minimum duration.

Lactation

The safe use of topical corticosteroids during lactation has not been established.

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. Administration of betamethasone valerate during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

If used during lactation betamethasone valerate should not be applied to the breasts to avoid accidental ingestion by the infant.

Females and Males of Reproductive Potential

There are no data in humans to evaluate the effect of topical corticosteroids on fertility.

4.7 Effects on ability to drive and use machines

There have been no studies to investigate the effect of betamethasone valerate on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical betamethasone valerate.

4.8 Undesirable effects

Stinging, burning, itching, irritation, dryness, or redness of the skin may occur when this medication is first applied to the skin. These effects should disappear in a few days as your body adjusts to the medication. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if any of these unlikely but serious side effects occur: stretch marks, skin thinning/discoloration, acne, extreme/unwanted hair growth, "hair bumps" (folliculitis).

Skin infections can become worse when this medication is used. Notify your doctor promptly if redness, swelling, or irritation does not improve.

Rarely, it is possible this medication will be absorbed from the skin into the bloodstream. This can lead to side effects of too much corticosteroid. These side effects are more likely in children, and in people who use this medication for a long time or over large areas of the skin. Tell your doctor right away if any of the following side effects occur: unusual/extreme tiredness, weight loss, headache, swelling ankles/feet, increased thirst/urination, vision problems.

A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

4.9 Overdose

Symptoms and signs

Topically applied betamethasone valerate may be absorbed in sufficient amounts to produce systemic effects. Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may occur (see section 4.8).

Treatment

In the event of overdose, betamethasone valerate should be withdrawn gradually by reducing the frequency of application, or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency.

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Benzomorphan derivatives}, ATC code: NO2ADO1

Mechanism of Action

Topical corticosteroids act as anti-inflammatory agents via multiple mechanisms to inhibit late phase allergic reactions including decreasing the density of mast cells, decreasing chemotaxis and activation of eosinophils, decreasing cytokine production by lymphocytes, monocytes, mast cells and eosinophils, and inhibiting the metabolism of arachidonic acid.

Pharmacodynamics

Topical corticosteroids have anti-inflammatory, antipruritic, and vasoconstrictive properties.

5.2 Pharmacokinetic properties

Absorption

Topical corticosteroids can be systemically absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption.

Distribution

The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary because circulating levels are well below the level of detection.

Metabolism

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolised, primarily in the liver.

Elimination

Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

5.3 Preclinical safety data

Subcutaneous administration of betamethasone valerate to mice or rats at doses ≥0.1 mg/kg/day or rabbits at doses ≥12 micrograms/kg/day during pregnancy produced foetal abnormalities including cleft palate and intrauterine growth retardation.

The effect on fertility of betamethasone valerate has not been evaluated in animals.

6 PHARMACEUTICAL PARTICULARS

6.2 List of excipients

Liquid Paraffin (Heavy)
Ceto-stearyl Alcohol
Stearic Acid
Cetomacrogol 1000
Propylene Glycol
Benzyl Alcohol
Purified Water

6.3 Incompatibilities

None have been reported or are known

6.4 Shelf life

36 Months

6.5 Special precautions for storage

Store below 30^{o}C in tight container protected from light and moisture.

6.6 Nature and contents of container and special equipment for use, administration or implantation

Betamethasone Cream is presented in 20g printed aluminium tube with a screw cap packed in hardboard carton with leaflet enclosed.

6.7 Special precautions for disposal and other handling

No special requirements.

7 APPLICANT/MANUFACTURER

Drugfield Pharmaceuticals Limited
Lynson Chemical Avenue Km38,
Lagos-Abeokuta Expressway
Sango-Otta, Ogun State, Nigeria
Tel: +2348033513989
Email:Info@drugfieldpharma.com