Drugfield Pharmaceuticals Limited

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

Betasalic® Ointment
(Betamethasone 0.1% $^{w}/_{w}$, Salicylic Acid 3% $^{w}/_{w}$)

1. NAME OF THE MEDICINAL PRODUCT

Betasalic (Betamethasone+ salicylic acid 0.1% $^{w}/_{w}$ + 3% $^{w}/_{w}$) Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram of ointment contains 0.1mg of betamethasone(as betamethasone valearate 1.20mg) and 30mg of salicylic acid.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment.
Smooth white, transluscent homogenous ointment

4. Clinical particulars

4.1 Therapeutic indications

Betamethasone valerate is a synthetic fluorinated corticosteroid. It is active topically and produces a rapid and sustained response in those inflammatory dermatoses that are normally responsive to topical corticosteroid therapy, and it is also effective in the less responsive conditions, such as psoriasis of the scalp, chronic plaque psoriasis of the hands and feet, but excluding widespread plaque psoriasis.
Topical salicylic acid softens keratin, loosens cornified epithelium and desquamates the epidermis.
This medicine is therefore indicated for the treatment of dry scaly skin.

4.2 Posology and method of administration

Adults
Once to twice daily. In most cases a thin film should be applied to cover the affected area twice daily. For some patients adequate maintenance therapy may be achieved with less frequent application.
It is recommended that betamethasone valerate+ salicylic acid is prescribed for 5 days, and that treatment is reviewed at that time.
Paediatric population
Dosage in children should be limited to 5 days.

4.3 Contraindications

Rosacea, acne, perioral dermatitis, perianal and genital pruritus. Hypersensitivity to any of the ingredients of the this medicine contraindicates its use as does tuberculous and most viral lesions of the skin, particularly herpes simplex, vacinia, varicella.

Betamethasone valerate + salicylic acid should not be used in napkin eruptions, fungal or bacterial skin infections without suitable concomitant anti-infective therapy.

4.4 Special warnings and precautions for use

This product contains a strong corticosteroid and should not be used under occlusion, as the keratolytic action of salicylic acid may enhance steroid absorption. Local and systemic toxicity can occur, especially with long-term continuous use, application to large or damaged skin areas, flexures, or with polythene occlusion. In children and on the face, treatment should be limited to 5 days, and prolonged therapy should be avoided in all patients. Topical corticosteroids must be used with caution in psoriasis due to risks of rebound flares, pustular psoriasis, and systemic toxicity. Avoid contact with eyes and mucous membranes. If irritation or sensitisation develops, discontinue treatment. Systemic absorption may lead to adrenal suppression and other corticosteroid-related side effects, particularly in infants and children, who are more susceptible due to higher skin surface area-to-weight ratio. Long-term use may also cause rebound flares or topical steroid withdrawal syndrome, especially on delicate skin sites. Visual disturbances such as blurred vision, cataract, or glaucoma have been reported with corticosteroid use and require ophthalmologic assessment. Patients should also be warned of a fire hazard, as fabrics in contact with the ointment can ignite easily.

4.5 Interaction with other medicinal products and other forms of interaction

Corticosteroids such as Hyrocortisone, Triamcinolone and Clobetasol: Concomitant use with other topical corticosteroids can increase the risk of adverse effects, such as skin atrophy.

Salicylates : Using with other salicylate- containing products can increase the risk of salicylate toxicity.

Retinoids such as Tretinion, Adapalene and Isotretinion: Using with retiniods can increase the risk of skin irritation.

Antifungals such as Clotrimazole and Miconazole: Using with betamethasone plus salicylic acis can increase the risk of skin irritation, such as redness, itching, and burning.

Antibiotics such as Neomycin and Bacitracin: Using with betamethasone plus salicylic acid can increase the risk of skin irritation, such as redness, itching, and burning.

4.6 Pregnancy and Lactation

Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. Drugs of this class should not be used extensively in large amounts or for prolonged periods of time in pregnant patients.
Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision

should be made to discontinue nursing or 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

This medicine is generally well tolerated and side effects are rare.
Continuous application without interruption may result in local atrophy of the skin, striae and superficial vascular dilation, particularly on the face.
Adverse reactions that have been reported with the use of topical corticosteroids include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis and allergic contact dermatitis.
The following may occur more frequently with the use of occlusive dressings: maceration of the skin, secondary infection, skin atrophy, striae and miliaria.
Vision blurred has been reported with corticosteroid use .
In addition, prolonged use of salicylic acid preparations may cause dermatitis.

4.9 Overdose

Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal functions resulting in secondary adrenal insufficiency, and produce manifestations of hypercorticism, including Cushing's disease.
Treatment: Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised.
With topical preparations containing salicylic acid excessive prolonged use may result in symptoms of salicyclism. Treatment is symptomatic. Measures should be taken to rid the body rapidly of salicylate. Administer oral sodium bicarbonate to alkalinise the urine and force diuresis.
The steroid content of each tube is so low as to have little or no toxic effect in the unlikely event of accidental oral ingestion.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamics properties

Pharmacotherapeutic group: Corticosteroids, dermatological preparations; Corticosteroids, potent, other combinations; ATC-Code: D07XC01

Betamethasone is classed as a potent corticosteroid (Class III).

This product contain the valerate ester of betamethasone which is a glucocorticoid exhibiting the general properties of corticosteroids, and salicylic acid which has keratolytic properties.

Salicylic acid is applied topically in the treatment of hyperkeratotic and scaling conditions where its keratolytic action facilitates penetration of the corticosteroid.
In pharmacological doses, corticosteroids are used primarily for their anti-inflammatory and/or immune suppressive effects.
Topical corticosteroids such as betamethasone valerate are effective in the treatment of a range of dermatoses because of their anti-inflammatory, anti-pruritic and vasoconstrictive actions. However, while the physiologic, pharmacologic and clinical effects of the corticosteroids are well known, the exact mechanisms of their action in each disease are uncertain.

5.2 Pharmacokinetic properties

Salicylic acid exerts only local action after topical application.
The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of the epidermal barrier and the use of occlusive dressings.
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.

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

Liquid paraffin, white soft paraffin

6.2 Incompatibilities

Not applicable

6.3 Shelf life

4 years

6.4 Special precautions for storage

Do not store above 30^{o}C. Keep out of reach and sight of children.

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

30g gram of ointment in aluminium tube.

6.6 Special precautions for disposal and other handling

No special requirements.

7. APPLICANT/MANUFACTURER

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