SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Betamethasone Basi 1mg/g Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 gram of ointment contains 1 mg of betamethasone (as valerate).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment for topical application on the skin.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Betamethasone is a powerful corticosteroid of topical action that produces satisfactory response in a short period of time in the inflammatory dermatoses that usually respond to the topical corticosteroid therapy and is also effective in more resistant situations, like psoriasis.

Betamethasone is indicated in the treatment of eczemas in children and adults, including atopic and discoid eczemas, pruritus nodularis, psoriasis (excluding generalized plaque psoriasis); neurodermatoses, including lichen simplex and lichen planus; seborrheic dermatitis; contact dermatitis; discoid lupus erythematosus; as adjuvant in the systemic corticosteroid therapy in generalised erythroderma; insect bites; miliaria rubra.

4.2 Posology and Method of Administration

Apply a small quantity in the affected area 2 to 3 times daily until improvements are seen. The improvements obtained can usually be kept applying then once daily, or even less commonly.
Betamethasone Basi is especially indicated in the dry, lichenified or scaly injuries, however it is not always that way.
In more resistant injuries, like in the tick plaques of psoriasis in the elbows and in the knees, the Betamethasone effect can be enhanced, if necessary, coating the area treated with a polyethylene film. Usually, the occlusive dressing during the night is enough to obtain satisfactory answer; after, the improvements obtained can generally be kept with the topical application without occlusion.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.
Rosacea, acne vulgaris or perioral dermatitis. Perianal and genital pruritus. Primary infection of the skin to virus (e.g..: herpes simplex, chickenpox). Hypersensitivity to the ingredients of the preparations. Betamethasone is not indicated in primary infections of the skin caused by fungi (e.g.: candidiasis, tinea) or bacteria (e.g.: impetigo) nor in dermatoses in children aged less than 1 year old including dipper dermatitis and eruption.

4.4 Special Warnings and Precautions for Use

When possible, the prolonged continuous therapy should be avoided, especially in the infants and children, because adrenal suppression can occur even without occlusion.

The face, more than any other part of the body, may present atrophic changes after the prolonged treatment with powerful topical corticosteroids. Attention should be given to this fact in the treatment of situations such as psoriasis, discoid lupus erythematosus and severe eczema. If applied on the eyelids, care should be taken to prevent it from entering in the eyes because it can originate glaucoma.

If used in the childhood, or in the face, the treatment must be limited to five days and no occlusive dressing should be used.

Topical corticosteroids may have risks in psoriasis due to several reasons including rebound recurrence, tolerance development, risk of generalised pustular psoriasis and development of local or systemic toxicity, due to the fact that the barrier function of the skin is changed. If used in psoriasis, careful observation of the patient is important.

Adequate antimicrobial therapy should be administrated whenever inflammatory injuries that become infected are being treated. Any spread of the infection requires the suspension of the topical corticosteroid therapy and the systemic administration of antimicrobials. The bacterial infection is facilitated by the heat and moisture conditions induced by the occlusive dressing, so the skin should be clean before applying a new dressing.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

No medical interactions with Betamethasone Basi are known.

4.6 Pregnancy and Lactation

The topical administration of corticosteroids in animals, during the pregnancy period, can cause abnormalities in the foetal development. For humans, the relevance of this observation has not been established; however, topical corticosteroids should not be used extensively, i.e., in large quantities or during long periods, during pregnancy.

4.7 - Effects on Ability to Drive and Use Machines

The cutaneous application of Betamethasone Basi does not affect the ability to drive and use machines.

4.8 Undesirable Effects

The intensive and prolonged treatment with very active corticosteroids may cause local atrophic changes in the skin such as thinning of the skin, striae and widening of the surface blood vessels, particularly with the use of occlusive dressing, or when skin folds are involved.

As with other topical corticosteroids, the prolonged use of large quantities or the treatment of very large areas may result in systemic absorption sufficient to produce the effect of hypercorticism and hypothalamic-pituitary-adrenal (HPA) axis suppression. This effect is more likely to happen in infants and children and if occlusive dressings are used. In infants, dippers can act as an occlusive dressing.

Pigmentation changes and hypertrichosis have been reported with topical corticosteroids.

It is thought that, in rare cases, the treatment of psoriasis with corticosteroids, or its suspension, caused the pustular form of the disease.

The preparations of Betamethasone are usually well-tolerated, but if hypersensitivity symptoms appear, the application should be immediately suspended.

Exacerbation of the symptoms may occur.

4.9 Overdose

The appearance of acute overdose is not likely, however, in the event of chronic overdose or abuse, symptoms of hypercorticism may appear and in this situation the topical corticosteroid should be suspended.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic classification:
Dermatologicals. Corticosteroids, dermatological preparations. Corticosteroids, potent (group III)
ATC Classification: D07AC01 BETAMETHASONE

5.1. Pharmacodynamic properties

Betamethasone valerate is a potent corticosteroid with topical anti-inflammatory activity.

5.2. Pharmacokinetic properties

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

Topical corticosteroids may be absorbed from normal intact skin. Dermal inflammation and/or other processes of dermatological disease increase the percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of the topical corticosteroids.

After dermal absorption, topical corticosteroids integrate pharmacokinetic routes similar to the ones of systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in several degrees. These are metabolised mainly in the liver and renally excreted.

5.3. Preclinical safety data

There are no relevant preclinical safety data additional to the ones present in other points of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Ointment: liquid paraffin and white soft paraffin.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

2 years.

6.4. Special Precautions for Storage

Store below 25ºC.

Betamethasone Basi should be kept out of the reach and sight of children.

6.5. Nature and Contents of Container

Aluminium tubes enamelled with internal coating of double layer epoxy-phenolic golden varnish. With high density polyethylene caps.

6.6. Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

06611/08077/REN/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Oct 19, 2021

10. DATE OF REVISION OF THE TEXT