BEZONE CREAM 0.1% W/W

NAME AND STRENGTH OF ACTIVE SUBSTANCE:
Betamethasone Valerate equivalent to
Betamethasone …….. 1.0mg

PRODUCT DESCRIPTION:
A white cream base in collapsible aluminium tubes.

PHARMACODYNAMICS:
Betamethasone Valerate is used in dermatology for its anti-inflammatory, antipruritic and vasoconstrictive action on the skin. As Betamethasone Valerate is a flourinated corticosteroid, it is metabolised more slowly in the skin and tends to be systemically absorbed to a greater extent, particularly to large areas of the body, or under an occlusive dressing or when the skin is broken.

PHARMACOKINETICS :
Systemic absorbed drug is usually metabolised in the liver.

INDICATION:
Bezone Cream is indicated for relief of acute or chronic inflammatory manifestation of corticosteroid – responsive dermatoses such as : localised neurodermatitis, psoriasis, atopic or seborrheic dermatitis, the inflammatory phase of xerosis, and anogenital pruritus. It is also indicated in allergic contact dermatitis or irritant dermatitis. In addition, the cream will cool and dry the acute inflammatory and exudative lesions.

RECOMMENDED DOSAGE:
The cream is used topically.
Adults : the cream is applied to the affected area two to four times a day.
Children: to be applied once a day.
Cream for occlusive dressing: gently rub a small amount of the cream to the affected area until it disappears. Re-apply the cream leaving a thin coating on the affected area and covered by piece of polyethylene sheet, or, for the hands and feet, polyethylene gloves or bags. As much as possible, the air between the skin and the polyethylene is expelled and the dressing sealed with adhesive tape. This left up to 48 hours and if necessary, renewed after the skin has been gently washed and dried.

ROUTE OF ADMINISTRATION:
Topical

CONTRAINDICATIONS:
Topical corticosteroids are contraindicated in viral diseases of the skin such as varicella and vaccina, and known hypersensitivity to any ingredients of the preparation.

WARNINGS AND PRECAUTIONS:
1. In general, corticosteroids should not be used in the presence of infection. Occasionally they may be used with the addition of a suitable antimicrobial substance in the treatment of infected skin but there is a risk of sensitivity reactions occurring.
2. Topical application of corticosteroids should not be made with an occlusive dressing to large areas of the body because of the increased risk of systemic toxicity.
3. Corticosteroids should not be applied to ulcers of the legs.
4. Long term topical use is best avoided especially in children and during pregnancy.

INTERACTIONS WITH OTHER MEDICAMENTS:
Not Known

STATEMENT ON USAGE DURING PREGNANCY:

Long term topical use is best avoided especially in children and during pregnancy.

ADVERSE EFFECTS/ UNDESIRABLE EFFECTS:

1. Infections such as pain, redness or pus-containing blisters.
2. Irritations such as burning, itching, blistering, or peeling not present before therapy.
3. With prolonged use and treatment of extensive areas:
   i) Moon face (feature of hypercorticism) due to systemic toxicity.
   ii) Reddish purple lines on arms, legs, trunk or groin.
   iii) Thinning of skin with easy bruising.

OVERDOSE AND TREATMENT:

Symptoms of toxicity that is associated with topical corticosteroids therapy may be characterised as either local or systemic.

Symptoms: As described under 'Adverse Effects'.

Treatment : Withdrawal/ discontinue the application of the preparation is usually all that is necessary. If infection develops, institute appropriate antimicrobial therapy.

DOSAGE FORMS AND PACKAGING AVAILABLE:

Pack size: Collapsible aluminium tubes : 15g & 50x15g

NAME AND ADDRESS OF MANUFACTURER/PRODUCT REGISTRATION HOLDER:

MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN.BHD. (101323-U)
Plot 14, Lebuhraya Kampung Jawa, 11900 Bayan Lepas,
Pulau Pinang, Malaysia.

DATE OF REVISION:

10/10/2022