

## **BETAVAL CREAM**

### **DESCRIPTION:**

A white smooth homogeneous mass

### **COMPOSITION:**

Each gm of the cream contains

Betamethasone (as Valerate) (Micronised) U.S.P. equivalent to 1.0mg of Betamethasone

### **ACTIONS & PHARMACOLOGY:**

The overall actions of corticosteroids are catabolic. Corticosteroids diffuse across cell membranes and complex with specific cytoplasmic receptors. These complexes then enter the nucleus, bind to D.N.A. (chromatin) and stimulate transcription of messenger R.N.A. (mRNA) and subsequent protein synthesis of various inhibitory enzymes responsible for anti-inflammatory effects of topical corticosteroids. The pharmacologic activity of topical corticosteroids is increased by several changes in molecular structure. Substitution or masking of 16 or 17 hydroxy groups with longer side chains such as acetone, propionate or valerate increase lipophilicity and subsequently stratum corneum penetration.

#### **Absorption:**

Absorbed systemically across the stratum corneum. Stratum corneum penetration is primarily enhanced by increasing skin hydration and or temperature, or by changes in molecular structure of the compound. Hydrating the skin with occlusive dressing such as plastic wrap, a tight-fitting diaper or one covered with plastic pants, plastic tape, or dermatological patches can increase corticosteroid penetration by up to tenfold. Intertriginous areas and the face also have inherently thinner skin, are more macerated and therefore, allow for increased absorption. Absorption of topical corticosteroids has been greatly increased by altering the product vehicle. Vehicles containing substances that solubilize the corticosteroid enhance absorption. Increasing the concentration of drug increases skin penetration. Decreasing drug particle size has been shown to increase topical bioavailability. Increased percutaneous absorption of corticosteroids also occurs when the skin or mucosa is abraded or inflamed, when body temperature is elevated, with prolonged use, or with extensive use.

#### **Biotransformation:**

Primarily in skin; once absorbed systemically, in the liver. Betamethasone is resistant to local metabolism in the skin. Repeated application results in a cumulative depot effect in the skin, which may lead to a prolonged duration of action, increased effects, and increased systemic absorption.

### **INDICATIONS:**

Relief of the inflammatory manifestations of corticosteroid- responsive dermatoses, eg eczema (atopic, infantile, nummular), contact dermatitis, seborrheic dermatitis, neurodermatitis, solar dermatitis, exfoliative dermatitis, stasis dermatitis, dermatitis due to radiation, intertrigo, otitis externa, psoriasis and anogenital and senile pruritis.

**CONTRAINDICATIONS:**

Contraindicated in those who are allergic to corticosteroids. Risk-benefit should be considered when the following medical problems exist. Infection at treatment site (may be exacerbated if no appropriate antimicrobial agent is used concurrently). Skin atrophy, pre-existing (may be exacerbated due to atrophigenic properties of corticosteroids). Contraindicated in infants under 1 year. Rosacea, acne vulgaris and perioral dermatitis. Primary cutaneous viral infections (eg. herpes simplex, chickenpox).

**SIDE EFFECTS:**

The incidence and severity of local or systemic side effects increase with factors that increase percutaneous absorption. Percutaneous absorption has resulted in systemic side effects such as hyperglycemia, glycosuria and hypothalamic-pituitary-adrenal (HPA) axis suppression. Less frequent side effects are burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection atrophy, striae, and miliaria.

**WARNING AND PRECAUTIONS:**

Topical corticosteroids should not be applied to the breasts prior to nursing. Children and adolescents have a large skin surface area to body weight ratio and less developed, thinner skin, which may result in absorption of greater amounts of topical corticosteroids compared with older patients. Absorption is also greater in premature infants than in full term newborns, due to inadequate development of the stratum corneum. Adrenal suppression, Cushing's syndrome, intracranial hypertension and growth retardation due to systemic absorption of topical corticosteroids have been documented in children. Therefore, special care must be exercised when these agents are used in children and growing adolescents, especially if factors that increase absorption are involved. The treated skin area should not be bandaged, or covered or wrapped as to be occlusive. Topical corticosteroids should be used with caution in patient with evidence of pre-existing skin atrophy. Blood and urine glucose concentration may be increased if significant absorption of the corticosteroids occurs. Gradual withdrawal of therapy by decreasing frequency of application may be necessary to avoid a rebound flare-up of certain conditions such as psoriasis. Tachyphylaxis may also result from continual usage

**PREGNANCY AND LACTATION:**

There is inadequate evidence of safety in human pregnancy.

**DOSAGE & ADMINISTRATION:**Usual adult dose

Apply a thin film to the affected skin area one to three times a day.

Usual pediatric dose

Apply a thin film to the affected skin area once a day. Do not use in or around eye.

If no improvement is seen within 2-4 weeks, reassessment of the diagnosis may be necessary.

**ROUTE OF ADMINISTRATION:**

Topical administration

**OVERDOSAGE & TREATMENT:**

Symptoms : No specific symptoms are reported.

Treatment : Since there is no specific antidote available, treatment is symptomatic, supportive and consists of discontinuance of topical corticosteroid therapy. If a local infection develops at the site of application, discontinue the therapy and institute appropriate antimicrobial therapy.

**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.

**PRESENTATION:**

Collapsible Aluminium tubes of 5g, 10g, 15g and 30g.  
HDPE Jar 500g

**STORAGE:**

Store in a cool dry place below 30°C.

Keep containers tightly closed.

Protect from light and freezing.

Keep medicine out of reach of children.

For external use only.

**MANUFACTURER & PRODUCT REGISTRATION HOLDER:**

Noripharma Sdn. Bhd. 200701034604 (792633-A)

Lot 5030, Jalan Teratai,

5 1/2 Mile off Jalan Meru,

Selangor Darul Ehsan MALAYSIA.

**DATE OF REVISION:**

August 2021