

### COMPOSITION

**Betnova Cream:** Each gram of cream contains Betamethasone Valerate BP equivalent to Betamethasone 1 mg.

Betnova Ointment: Each gram of ointment contains Betamethasone Valerate

BP equivalent to Betamethasone 1 mg.

#### **PHARMACOLOGY**

Betamethasone Valerate is an active corticosteroid with topical anti-inflammatory activity.

#### INDICATION

Betamethasone Valerate cream/ ointment is indicated for the treatment of eczema in children and adults, including atopic and discoid eczemas, prurigo nodularis, psoriasis (excluding widespread plaque psoriasis); neurodermatitis, including lichen simplex, lichen planus; seborrhoeic dermatitis; contact sensitivity reactions; discoid lupus erythematosus.

#### DOSAGE AND ADMINISTRATION

A small quantity of Betamethasone Valerate cream/ ointment should be applied and rubbed gently to the affected area 2 or 3 times daily until improvement occurs. Children: Courses should be limited to five days.

### CONTRAINDICATION

Betamethasone Valerate is contraindicated in patients with a history of hypersensitivity to any of the components of the preparation.

### **WARNING AND PRECAUTION**

Avoid contact with the eyes. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.

### SIDE EFFECT

Burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria may be reported.

### **USE IN PREGNANCY AND LACTATION**

There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, this cream/ ointment should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Caution should be exercised when topical corticosteroids are administered to a nursing woman.

# **USE IN CHILDREN**

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. Administration of topical corticosteroids to pediatric patients should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

# **OVER DOSAGE**

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects.

## STORAGE CONDITION

Keep below 30°C temperature, protected from light. Do not freeze. Keep out of the reach of children.

### **HOW SUPPLIED**

**Betnova Cream:** Each box contains a tube of 15 gm Betnova Cream. **Betnova Ointment:** Each box contains a tube of 15 gm Betnova Ointment.

