

Betnova-N

Betamethasone 0.1% W/W and Neomycin Sulfate BP 0.5% W/W

COMPOSITION

Betnova-N Cream: Each gram of cream contains Betamethasone Valerate BP equivalent to Betamethasone 1 mg and Neomycin Sulfate BP 5 mg.

PHARMACOLOGY

Betamethasone Valerate is very active fluorinated corticosteroid for topical use. At normal dosage, even often prolong use, it does not depress the suprarenal glands and one may consider its systemic activity as practically nil.

Neomycin Sulfate is a broad spectrum, bactericidal antibiotic effective against the majority of bacteria commonly associated with skin infections.

INDICATION

Severe inflammatory skin disorders in patients unresponsive to less potent corticosteroids. These disorders include: Atopic eczema, contact dermatitis, dyshidrosis, exfoliative dermatitis, infantile eczema, intertrigo, neurodermatitis, pruritus ani, pruritus vulvae, psoriasis, seborrheic dermatitis, solar dermatitis.

DOSAGE AND ADMINISTRATION

Apply Betnova-N cream sparingly 2-3 times daily, reducing frequency as condition responds.

CONTRAINDICATION

Untreated bacterial, fungal or viral skin lesions, acne and perioral dermatitis.

WARNING AND PRECAUTION

Long-term continuous topical therapy should be avoided where possible, particularly in infants and children. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might occur.

SIDE EFFECT

Skin: Burning itching, irritation, dryness, folliculitis, hypopigmentation, perioral dermatitis, allergic contact dermatitis, hypertrichosis, acneiform eruptions. With occlusive dressings: maceration of skin, secondary infection, atrophy, striae, miliaria.

USE IN PREGNANCY AND LACTATION

There is little information to demonstrate the possible effect of topically applied Betamethasone and Neomycin in pregnancy and lactation. However, Neomycin Sulfate present in maternal blood can cross the placenta and may give rise to a theoretical risk of foetal toxicity, thus use of this medicinal product is not recommended in pregnancy or lactation.

USE IN CHILDREN

Betnova-N is suitable for use in children (2 years and over) at the same dose as adults. When used in children, courses should be limited to 5 days, if possible. A possibility of increased absorption exists in very young children, thus this medicinal product is not recommended for use in neonates and infants younger than 2 years of age.

OVERDOSE

Acute overdosage is very unlikely to occur. However, in the case of chronic overdosage or misuse the features of Cushing's syndrome may appear and in this situation topical steroids should be discontinued gradually under medical supervision. Also, consideration should be given to significant systemic absorption of Neomycin Sulfate. If this is suspected, use of the product should be stopped and the patient's general status, hearing acuity, renal and neuromuscular functions should be monitored.

STORAGE CONDITION

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

HOW SUPPLIED

Betnova-N Cream: Each box contains a tube of 10 gm Betnova-N Cream.