PRESCRIBING INFORMATION

TEVA-ECTOSONE

Betamethasone Valerate Cream

0.05 % and 0.1 %

BP

Mild and Regular Cream

Betamethasone Valerate Lotion

0.05 % and 0.1 %

USP

Mild and Regular Lotion

Topical corticosteroid

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INDICATIONS AND CLINICAL USE

For the topical management of allergic and inflammatory dermatoses responsive to corticosteroid therapy. These disorders include: psoriasis, atopic eczema, infantile eczema, nummular eczema, pruritus ani and vulvae, neurodermatitis (lichen simplex chronicus), intertrigo, contact dermatitis, seborrheic dermatitis, exfoliative dermatitis, solar dermatitis, stasis dermatitis and dyshidrosis. Refractory psoriasis may be treated with Ectosone regular especially in conjunction with the hydration technique of occlusive dressings.

Ectosone mild contains a lower concentration (half strength) of betamethasone and is indicated for maintenance therapy after the acute phase has been brought under control, for less severe conditions and for extensive lesions involving large areas of the body surface.

CONTRAINDICATIONS

Contraindicated in the treatment of tuberculosis of skin, herpes simplex, varicella, vaccinia, superficial fungus of yeast infections. Application in or near the eyes should be avoided. Patients with a history of sensitivity reactions to any of its components.

PRECAUTIONS

Corticosteroids are known to be absorbed percutaneously in patients under prolonged treatment, with extensive body surface treatment or particularly in those using the occlusive dressing technique on large areas of the body. In such cases, it is recommended that kidney function studies such as BUN be carried out prior to treatment and regularly throughout the course of the treatment.

Pregnancy and Lactation:

The use of any drug during pregnancy and the lactation period or in women of childbearing age requires that the potential benefits of the drug be weighed against the possible hazards to the fetus or infant. Although topical corticosteroid have not been reported to have an adverse effect on the fetus, the safety of their use in pregnant patients has not been definitely established. Therefore they should not be used extensively in large amounts or for prolonged periods of time in pregnant patients.

Since it is not known whether topical administration of corticosteroids can results in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Children:

Any of the side effects that have been reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children. Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio. HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanel, headaches and bilateral papilledema. Use of topical corticosteroids in children should be limited to the least amount compatible with an effective therapeutic regimen. The topical corticosteroid therapy may interfere with growth and development of children.

When long-term topical treatment under occlusive dressings is necessary, small dosages, rotation of sites and intermittent therapy should be considered.

Patients should be advised to inform subsequent physicians of the prior use of corticosteroids.

In the presence of infection, **TEVA-ECTOSONE** preparations should be superseded by suitable antibacterial agents until the infection has cleared.

The possibility of sensitivity reactions to any of the product's components should be kept in mind.

ADVERSE REACTIONS

With use of topical corticosteroids, local reactions have been reported, namely, burning sensation, itching, irritation, dryness, hypertrichosis, acneiform eruptions, and hypopigmentation. Striae, secondary infection, atrophy, miliaria, pyodermas also occur but more frequently with use of occlusive dressings. Contact sensitivity to a particular dressing material or adhesive may occur occasionally.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Symptoms:

Excessive and prolonged use of topical corticosteroids can suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency and produce manifestations of hypercorticism including Cushing's disease.

Treatment:

Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary, in case of chronic toxicity, slow withdrawal of corticosteroids is advised.

DOSAGE

Apply a small amount on the affected skin 2 or 3 times daily. Refractory lesions of psoriasis and other deep-seated dermatoses such as lichen simplex chronicus, hypertrophic lichen planus, atopic dermatitis, chronic eczematous and lichenified hand eruptions, and recalcitrant pustular eruptions on the palms and soles will respond better to topical corticosteroids when used with the hydration technique of occlusive dressing.

This technique reduces evaporation from the skin by means of a closed impermeable dressing over the lesion.

Occlusive dressing technique: **1.** Apply a thick layer of the cream over the entire surface of the lesion under a light gauze dressing and then cover it with a pliable, transparent, impermeable, plastic material well beyond the treated area. **2.** Seal the edges to the normal skin by adhesive tape or other means. **3.** Leave the dressing in place 1 to 3 days and repeat the procedure 3 or 4 times as needed. With this method of treatment, marked improvement often is seen in a few days.

Occasionally, a miliary eruption or folliculitis develops in the skin under the occlusive dressing requiring removal of the plastic covering.

SUPPLIED:

TEVA-ECTOSONE Regular Cream: Each gram contains: 0.1% of betamethasone (as betamethasone valerate USP) in a water-miscible base. Jar of 450 g. Store at room temperature (15-30^{o}C).

TEVA-ECTOSONE Mild Cream: Each gram contains: 0.05% of Betamethasone (as betamethasone valerate USP) in a water-miscible base. Jar of 450 g. Store at room temperature (15-30^{o}C).

TEVA-ECTOSONE Regular Lotion: Each gram contains: 1.22 mg of betamethasone valerate USP (equivalent to 1 mg (0.1% of betamethasone). Also contains isopropanol. Bottle of 60 mL. Store between 15-30^{o}C). Protect from freezing.

TEVA-ECTOSONE Mild Lotion: Each gram contains: betamethasone valerate USP 0.61 mg (equivalent to betamethasone 0.5 mg (0.05%). Also contains isopropanol. Bottle of 60 mL. Store between 15-30^{o}C. Protect from freezing.