

PRESCRIBING INFORMATION

TEVA-ECTOSONE

Betamethasone Valerate USP

0.1%

Scalp Lotion

Topical Corticosteroid

Teva Canada Limited
30 Novopharm Court
Toronto, Ontario
Canada M1B 2K9
www.tevacanada.com

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TEVA-ECTOSONE **Betamethasone Valerate USP** **0.1%**

scalp lotion

Topical corticosteroid

INDICATIONS AND CLINICAL USE

For the management of dermatoses of the scalp. May also be used in corticosteroid responsive dermatoses.

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 an history of sensibility reactions to any of its components.

WARNINGS

This lotion contains isopropyl alcohol and may cause stinging or burning upon application to abraded or sunburned skin. Do not use in or near the eyes.

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 corticosteroids 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 result 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. Use of the topical corticosteroid therapy may interfere with growth and development of children.

When a 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, 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, folliculitis, and pyodermas also occur but more frequently with use of occlusive dressings. Contact sensitivity to a particular dressing material or adhesive may occur occasionally.

DOSAGE

Shake well before using. Apply a small amount to the affected skin 2 or 3 times daily or as prescribed by the physician. 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 as described in the **TEVA-ECTOSONE** Prescribing Information.

SUPPLIED: Each g contains: 1.22 mg betamethasone valerate USP, equivalent to 1 mg of betamethasone in a base of carboxypolymethylene, isopropyl alcohol and water. Plastic squeeze bottles of 30 and 75 mL. Store at temperature between 15-30°C. Protect from freezing.