Mometasone Furoate Topical Solution USP, 0.1% For Dermatologic Use Only Not for Ophthalmic Use Rx Only

DESCRIPTION Mometasone furoate topical solution USP, 0.1%, contains mometasone furoate, USP for dermatologic use. Mometasone furoate topical solution is a synthetic corticosteroid with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing’s syndrome, hyperglycemia, and glucosuria may also be produced in some patients. Systemic absorption of topical corticosteroids while on treatment. Patients apply topical corticosteroids to a large surface area or areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. This may be done by using the ACTH stimulation test, A.M. plasma cortisol, and urinary free cortisol tests.

In a study evaluating the effects of mometasone furoate lotion on the hypothalamic-pituitary-adrenal (HPA) axis, 15 mL was applied twice daily for 30 days to 7-day to 24-month-old infants with atopic dermatitis, were enrolled in an open-label, hypothalamic-pituitary-adrenal (HPA) axis safety study. Mometasone furoate topical solution USP, 0.1% caused cleft palate at subcutaneous doses of 60 mcg/kg and above. Fetal survival was reduced at 180 mcg/kg. No toxicity was observed at 20 mcg/kg. (Doses of 20, 60, and 180 mcg/kg were derived from the estimated maximum clinical topical dose from mometasone furoate topical solution USP, 0.1% on a mcg/m2 basis). In an oral study, mometasone furoate increased resorptions and caused cleft palate and/or head malformations (hydrocephaly and dorum head) at 700 mcg/m2 (approximately 0.2 times the estimated maximum clinical topical dose from mometasone furoate topical solution USP, 0.1% on a mcg/m2 basis). In mice, mometasone furoate caused cleft palate at subcutaneous doses of 60 mcg/kg and above. Fetal survival was reduced at 180 mcg/kg. No toxicity was observed at 20 mcg/kg. (Doses of 20, 60, and 180 mcg/kg were derived from the estimated maximum clinical topical dose from mometasone furoate topical solution USP, 0.1% on a mcg/m2 basis).

Mometasone furoate increased chromosomal aberrations in an in vitro Chinese hamster lung cell assay. Mometasone furoate was not mutagenic in the Ames test or mouse lymphoma assay. Mometasone furoate did not induce chromosomal aberrations in vivo in rat hepatocytes. In vivo studies in rats, impairment of fertility was not produced in male or female rats by subcutaneous doses up to 15 mcg/kg (approximately 0.01 times the estimated maximum clinical topical dose from mometasone furoate topical solution USP, 0.1% on a mcg/m2 basis). Pregnancy: Teratogenic Effects: Pregnancy Category C: Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have also shown decreased fetal weights after dermal application in laboratory animals. When administered to pregnant rats, rabbits, and mice, mometasone furoate produced fetal malformations. The doses that produced malformations also decreased fetal growth, as measured by lower birth weights and reduced fetal body weights. Such changes may also cause dystocia and related complications when administered to rats during the end of pregnancy. In mice, mometasone furoate caused cleft palate at subcutaneous doses of 60 mcg/kg and above. Fetal survival was reduced at 180 mcg/kg. No toxicity was observed at 20 mcg/kg. (Doses of 20, 60, and 180 mcg/kg were derived from the estimated maximum clinical topical dose from mometasone furoate topical solution USP, 0.1% on a mcg/m2 basis).

Mometasone furoate topical solution USP, 0.1% should not be used in the treatment of diaper dermatitis.

Geriatric Use: Clinical studies of mometasone furoate topical solution USP, 0.1% did not include sufficient number of subjects aged 65 years of age or older to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses in the elderly and younger subjects. In general, dose selection for an elderly patient should be based on age.

ADVERSE REACTIONS In clinical studies involving 209 patients, the incidence of adverse events associated with the use of mometasone furoate topical solution USP, 0.1% during a clinical study, in 14% of 65 pediatric patients 6 months to 2 years of age; decreased glucocorticoid levels, 4; paraparesis, 2; dry mouth, 1; an unspecified endocrine disorder, 1; pruritis, 1; and an unspecified skin disorder. 1. The following signs of skin toxicity were also observed in this population. (see PRECAUTIONS - Pediatric Use).

Ocular effects: Infrequent adverse reactions included conjunctivitis, sterile conjunctival exudate, and follicular conjunctivitis. Occasional adverse reactions included epiphora, corneal pigmentation, and transient erythema of the conjunctiva.

DOSAGE AND ADMINISTRATION Apply a few drops of mometasone furoate topical solution USP, 0.1% to the affected skin area once or twice daily. For the effective and economical use, hold the nozzle of the bottle very close to the affected area. If the seborrheic dermatitis is more extensive, the affected skin area can be covered with a cloth or occlusive dressing (see PRECAUTIONS - Pediatric Use). When administered topically, corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have also shown decreased fetal weights after dermal application in laboratory animals. When administered to pregnant rats, rabbits, and mice, mometasone furoate produced fetal malformations. The doses that produced malformations also decreased fetal growth, as measured by lower birth weights and reduced fetal body weights. Such changes may also cause dystocia and related complications when administered to rats during the end of pregnancy. In mice, mometasone furoate caused cleft palate at subcutaneous doses of 60 mcg/kg and above. Fetal survival was reduced at 180 mcg/kg. No toxicity was observed at 20 mcg/kg. (Doses of 20, 60, and 180 mcg/kg were derived from the estimated maximum clinical topical dose from mometasone furoate topical solution USP, 0.1% on a mcg/m2 basis). In an oral study, mometasone furoate increased resorptions and caused cleft palate and/or head malformations (hydrocephaly and dorum head) at 700 mcg/m2 (approximately 0.2 times the estimated maximum clinical topical dose from mometasone furoate topical solution USP, 0.1% on a mcg/m2 basis).

Mometasone furoate topical solution USP, 0.1% could increase the risk of hyperglycemia in patients with diabetes and in patients at risk for diabetes.

Follow-up testing 2 to 4 weeks after stopping treatment, available for 8 of the patients, demonstrated suppressed HPA axis function in one patient, and using these criteria.

INDICATIONS AND USAGE Mometasone furoate topical solution USP, 0.1%, is intended for the treatment of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Since safety and efficacy of mometasone furoate topical solution USP, 0.1%, have not been established in pediatric patients below 12 years of age, its use in this age group is not recommended. (see PRECAUTIONS - Pediatric Use).

CONTRAINDICATIONS Mometasone furoate topical solution USP, 0.1% is contraindicated in those patients with a history of hypersensitivity to any of the components in the preparation.