reassessment of the diagnosis may be necessary.

However, corticosteroids are thought to act by inhibiting the release of their common mediator, prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Anaphylactic shock can be achieved. If no improvement is seen within 2 weeks, treatment beyond 2 weeks at a time and only small areas should be treated at any one time due to the increased risk of HPA suppression.

Halobetasol Propionate Ointment produced HPA axis suppression when used in divided doses at 7 grams per day for one week in patients with psoriasis. These effects were reversible upon discontinuation of treatment. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid. Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infringe, signs and symptoms of glucocorticoid insufficiency may occur requiring supplemental systemic corticosteroids. For information on systemic supplementation, see prescribing information for those products.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios (see PRECAUTIONS: Pediatric Use). If irritation develops, Halobetasol Propionate Ointment should not be used other than that for which it was prescribed.

CONTRAINDICATIONS

Halobetasol Propionate Ointment is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

PRECAUTIONS

General

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

Patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. This may be done by using the ACTH stimulation, A.M. plasma cortisol, and urinary free-cortisol tests. Patients receiving super potent corticosteroids should not be treated for more than 2 weeks at a time and only small areas should be treated at any one time due to the increased risk of HPA suppression.

Clinically significant adrenal suppression has been reported with the long-term use of high potency topical corticosteroids, particularly those containing fluocinolone acetonide,alcortin A, paramethasone, or triamcinolone. The potential for glucocorticoid insufficiency should be considered in patients receiving long-term therapy with high potency corticosteroids. If adrenocortical suppression occurs, it should be promptly diagnosed and the patient treated appropriately. The possibility of Cushing's syndrome should be considered if patients treated with high potency topical corticosteroids exhibit signs and symptoms of adrenocortical insufficiency, such as hypotension, hypoglycemia, and shock.

Steroid-responsive dermatoses. Treatment beyond 2 weeks at a time and only small areas should be treated at any one time due to the increased risk of HPA suppression.
Laboratory Tests
The following tests may be helpful in evaluating patients for HPA axis suppression: ACTH-stimulation test; A.M. plasma cortisol test; Urinary free-cortisol test.

Carcinogenesis, Mutagenesis and Impairment of Fertility
Long-term animal studies have not been performed to evaluate the carcinogenic potential of halobetasol propionate. Positive mutagenicity effects were observed in in vitro genotoxicity assays. Halobetasol propionate was positive in a Chinese hamster micronucleus test, and in a mouse lymphoma gene mutation assay, in vitro. Studies in the rat following oral administration at doses levels up to 50 mg/kg/day indicated no impairment of fertility or general reproductive performance.

In other genotoxicity testing, halobetasol propionate was not found to be genotoxic in the Ames/Salmonella assay, in the sister chromatid exchange test in somatic cells of Chinese hamster, in chromosome aberration studies of germinal and somatic cells of rodents, and in a mammalian spot test to determine point mutations.

Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children. Manifestations of adrenal suppression in children include low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Geriatric Use
Of approximately 850 patients treated with Halobetasol Propionate Ointment in clinical studies, 21% were 61 years and over and 6% were 71 years and over. No overall differences in safety or effectiveness were observed between these patients and younger patients; and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Adverse Reactions
In controlled clinical trials, the most frequent adverse events reported for Halobetasol Propionate Ointment included stinging or burning in 1.6% of the patients. Less frequently reported adverse reactions were pustulosis, erythema, skin atrophy, hirsutism, acne, itching, secondary infection, telangiectasia, urticaria, dry skin, milia, parabiosis, and rash.

Ophthalmocele was seen in rats, but not in rabbits. There are no adequate and well-controlled studies of the teratogenic potential of halobetasol propionate in pregnant women. Halobetasol Propionate Ointment should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Halobetasol propionate has been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. Halobetasol propionate was embryotoxic in rabbits but not in rats.

Nursing Mothers
Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other undesired effects. It is not known whether topically administered corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when Halobetasol Propionate Ointment is administered to a nursing woman.

Pediatric Use
Safety and effectiveness of Halobetasol Propionate Ointment in pediatric patients have not been established and use in pediatric patients under 12 is not recommended. Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing’s syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during or after withdrawal of treatment. Adverse effects, including striae have been reported with inappropriate use of topical corticosteroids in infants and children.

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

OVERDOSAGE
Topically applied Halobetasol Propionate Ointment can be absorbed in sufficient amounts to produce systemic effects (see PRECAUTIONS).

Dosage and Administration
Apply a thin layer of Halobetasol Propionate Ointment to the affected skin once or twice daily, as directed by your physician, and rub in gently and completely.

How Supplied
Halobetasol Propionate Ointment, 0.05% is supplied in the following tube sizes: 15 g (NDC 0713-0639-15) 50 g (NDC 0713-0639-86)

Storage
Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature]

Manufactured by:
G&W Laboratories, Inc.
111 Coolidge St.
South Plainfield, NJ 07080
8-063092W
8-063092W2
Rev. 04/2015