

254172 LFLT FLUOCINONIDE OINTMENT USP 0.05% US (FRONT)

Market/Customer :	US	Location :	Pithampur		
Prepared On :	25/01/2018	Version No. :	04		
Product Name :	LFLT FLUOCINONIDE OINTMENT USP 0.05% US				
Material Code :	254172	Supersedes Material code :	NA		
Open Size :	210 x 141 mm (L x W)	Barcode value :	NA		
Folded Size :	210 x 23.5 mm (L x W)	Barcode Type (Ex. NDC, PZN, EAN-13)	NA		
Substrate :	GSM : 60 gsm	Component :	Pack Insert		
	Paper : Maplitho paper	Font Size :	6 PT		
Font Name :	Helvetica condensed	Gluing :	NA		
Perforation :	NA	Pharma Code :	4829		
Cover Page Substrate :	NA				
Pantone Colours :	Black				
Reason for Change :	Artwork for commercial launch.				

141 mm

	Laboratory Tests The following tests may be helpful in evaluating the HPA axis suppression: Urinary free cortisol test ACTH stimulation test
	Carcinogenesis & Mutagenesis & Impairment Of Fertility Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.
	Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results. Pregnancy Category C Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well- controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.
	Nursing Mothers It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.
	Pediatric Use Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalmic-pituitary-adrenal (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, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in childreninclude linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.
	Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.
	ADVERSE REACTIONS The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: Burning Perioral dermatitis Itching Allergic contact dermatitis Irritation Maceration of the skin
	Dryness Secondary infection Folliculitis Skin atrophy Hypertrichosis Striae Acneiform eruptions Miliaria
	Hypopigmentation OVERDOSAGE Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see PRECAUTIONS).
	DOSAGE AND ADMINISTRATION Fluocinonide Ointment USP, 0.05% is generally applied to the affected area as a thin film from two to four times daily depending on the severity of the condition.
	Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions. If an infection develops, the use of the occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted. HOW SUPPLIED
	Fluocinonide Ointment, 0.05% is supplied in 15 g Tube - NDC 43386-095-60 30 g Tube - NDC 43388-095-62
	60 g Tube - NDC 43386-095-61 Store at 20° to 25°C (68° to 77°F). Avoid temperature over 30°C (86°F). Manufactured for: Lupin Pharmaceuticals, Inc.
	Baltimore, Maryland 21202 United States Manufactured by:
	Lupin Limited Pithampur (M.P.) 454 775, INDIA Revised: January 2018 ID#: 254172

254172 LFLT FLUOCINONIDE OINTMENT USP 0.05% US (BACK)

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Unicorn Creation D/Lupin/Regulatory/US/R	- Fluocinonide Ointment USP/				