

CLOBETASOL PROPIONATE- clobetasol propionate ointment
Aleor Dermaceuticals Limited

Clobetasol Propionate Ointment USP, 0.05%
(Potency expressed as clobetasol propionate)

Rx Only
FOR DERMATOLOGIC USE ONLY.
NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

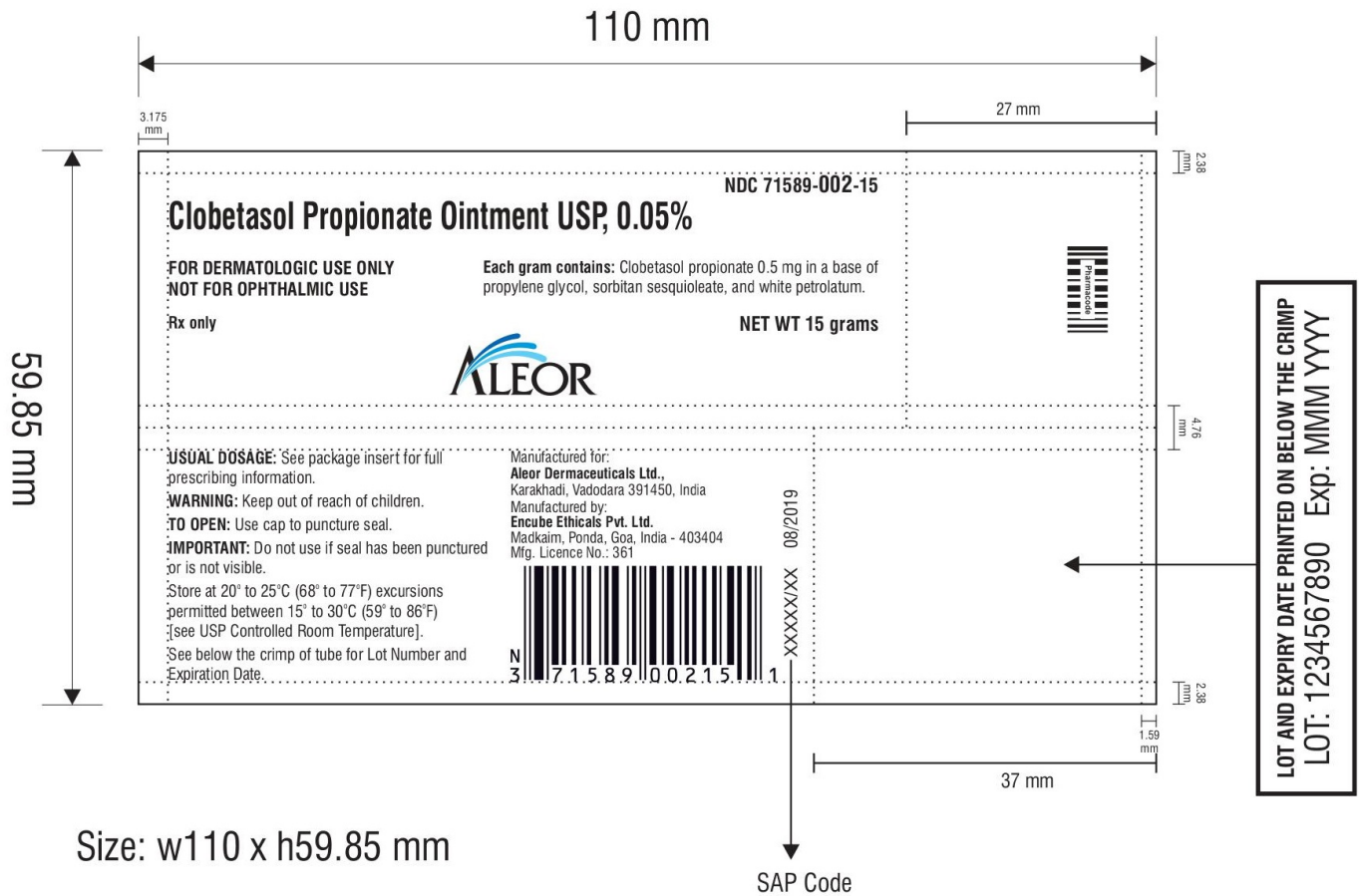
NDC 71589-002-15

Aleor Dermaceuticals Ltd.

Clobetasol Propionate Ointment USP, 0.05%

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NET WT 15 grams



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Aleor Dermaceuticals Ltd.

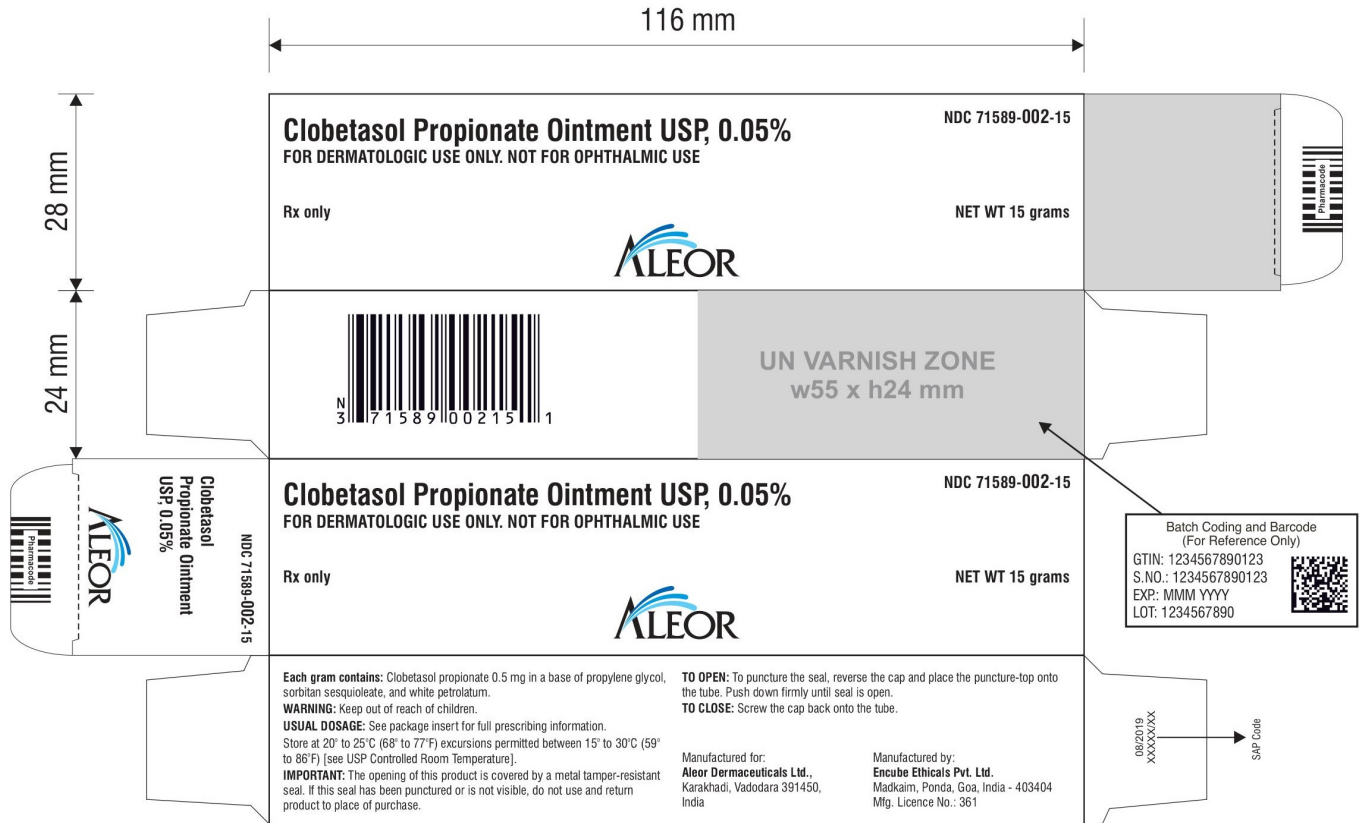
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Dimensions: L116x W28x H24

CLOBETASOL PROPIONATE

clobetasol propionate ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:71589-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOBETASOL PROPIONATE (UNII: 779619577M) (CLOBETASOL - UNII:ADN79D536H)	CLOBETASOL PROPIONATE	0.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71589-002-15	1 in 1 CARTON	03/12/2019	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:71589-002-30	1 in 1 CARTON	03/12/2019	
2		30 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:71589-002-45	1 in 1 CARTON	03/12/2019	
3		45 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:71589-002-60	1 in 1 CARTON	03/12/2019	
4		60 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211800	03/12/2019	

Labeler - Aleor Dermaceuticals Limited (871411532)

Registrant - Aleor Dermaceuticals Limited (871411532)

Establishment

Name	Address	ID/FEI	Business Operations
Encube Ethicals Pvt. Ltd.		725076298	MANUFACTURE(71589-002)

Revised: 8/2019

Aleor Dermaceuticals Limited