

**FLUOCINONIDE- fluocinonide solution**  
**Cadila Healthcare Limited**

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**Fluocinonide topical solution USP, 0.05%**

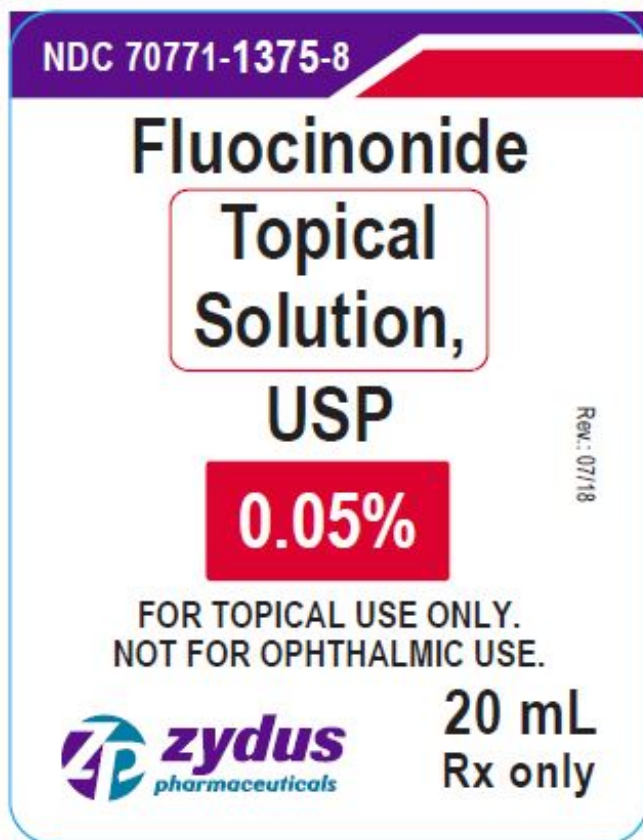
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1375-8

Fluocinonide topical solution USP, 0.05%

Rx only

20 mL



Front Label

**Each mL contains:** 0.5 mg Fluocinonide, USP in a solution of citric acid monohydrate, dehydrated alcohol (35%), diisopropyl adipate, propylene glycol and purified water.

**USUAL DOSAGE:** A small amount should be applied to the affected area two to four times daily, as needed. See package insert for full prescribing information.

**Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Avoid excessive heat above 40°C (104°F).**

Rev: 07/18

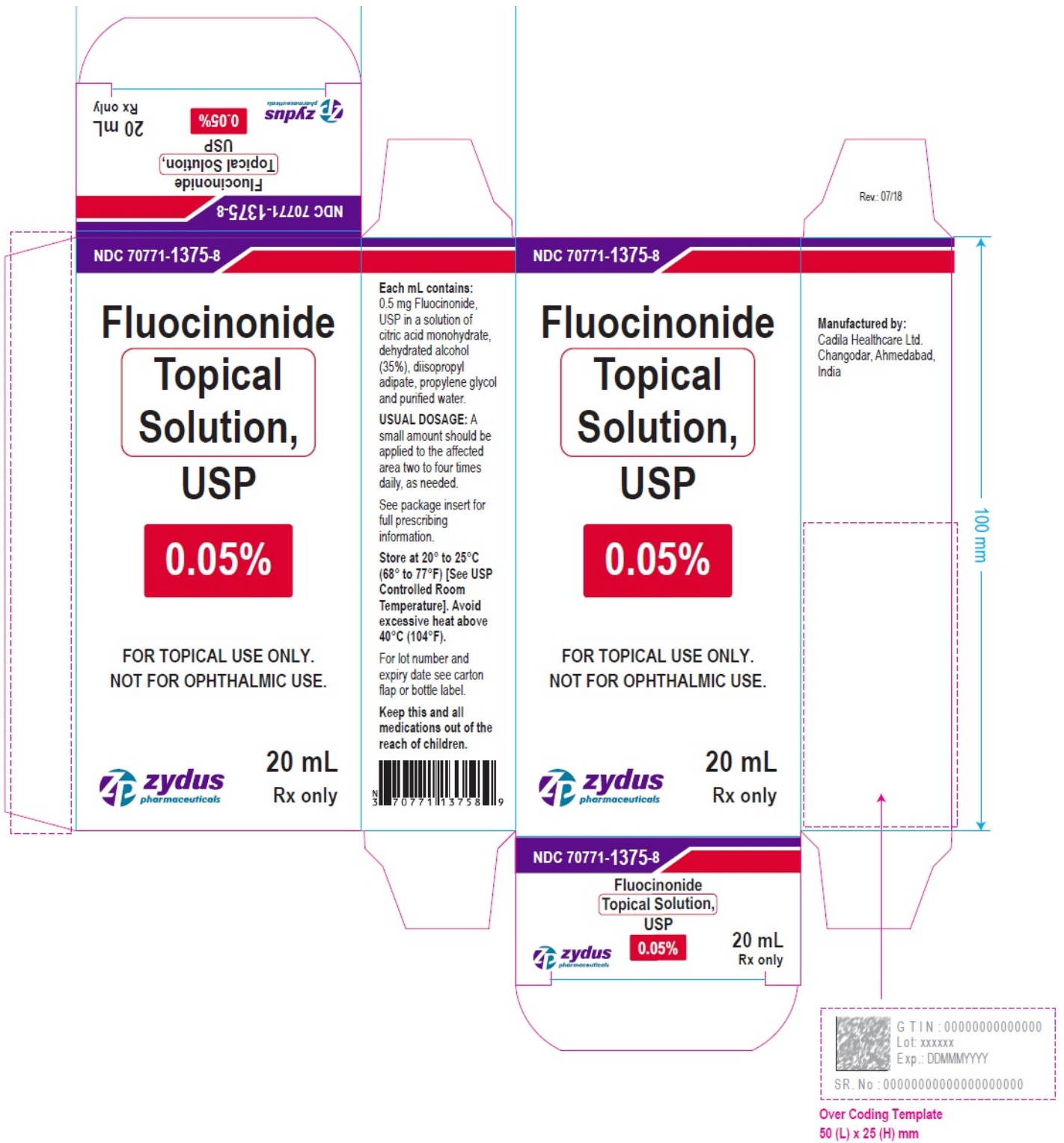
For lot number and expiry date see carton flap or bottle label.

**Keep this and all medications out of the reach of children.**

**Manufactured by:**  
Cadila Healthcare Ltd.  
Changodar, Ahmedabad, India



Back Label



**FLUOCINONIDE**  
fluocinonide solution

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1375
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
FLUOCINONIDE (UNII: 2W4A77YPAN) (FLUOCINONIDE - UNII:2W4A77YPAN)	FLUOCINONIDE	0.5 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1375-8	20 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	
2	NDC:70771-1375-3	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208948	11/01/2018	

**Labeler** - Cadila Healthcare Limited (918596198)**Registrant** - Cadila Healthcare Limited (650650802)**Establishment**

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		650650802	ANALYSIS(70771-1375) , MANUFACTURE(70771-1375)

Revised: 7/2020

Cadila Healthcare Limited