FLUOCINONIDE- fluocinonide solution
Zydus Lifesciences Limited

Fluocinonide topical solution USP, 0.05%

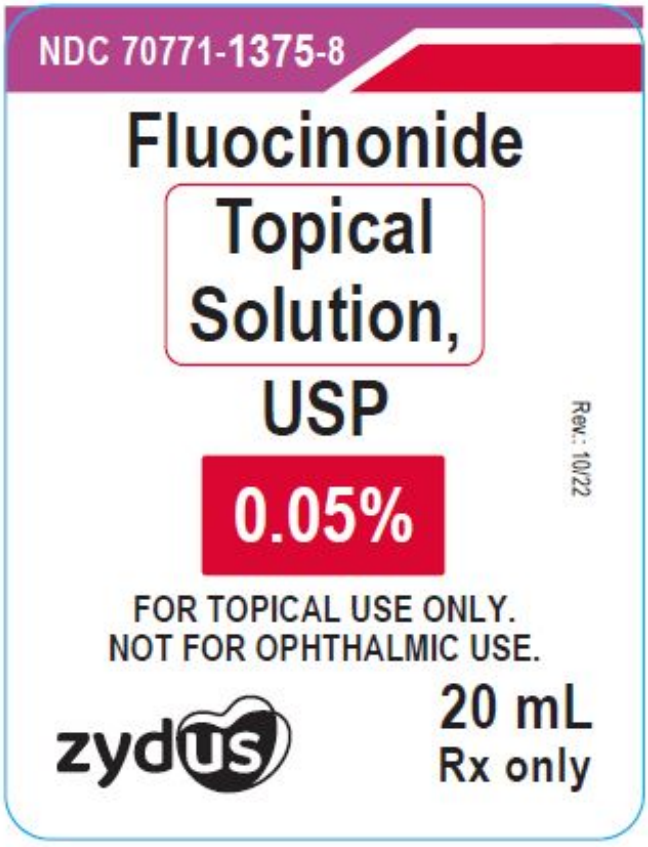
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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

Rev: 10/22

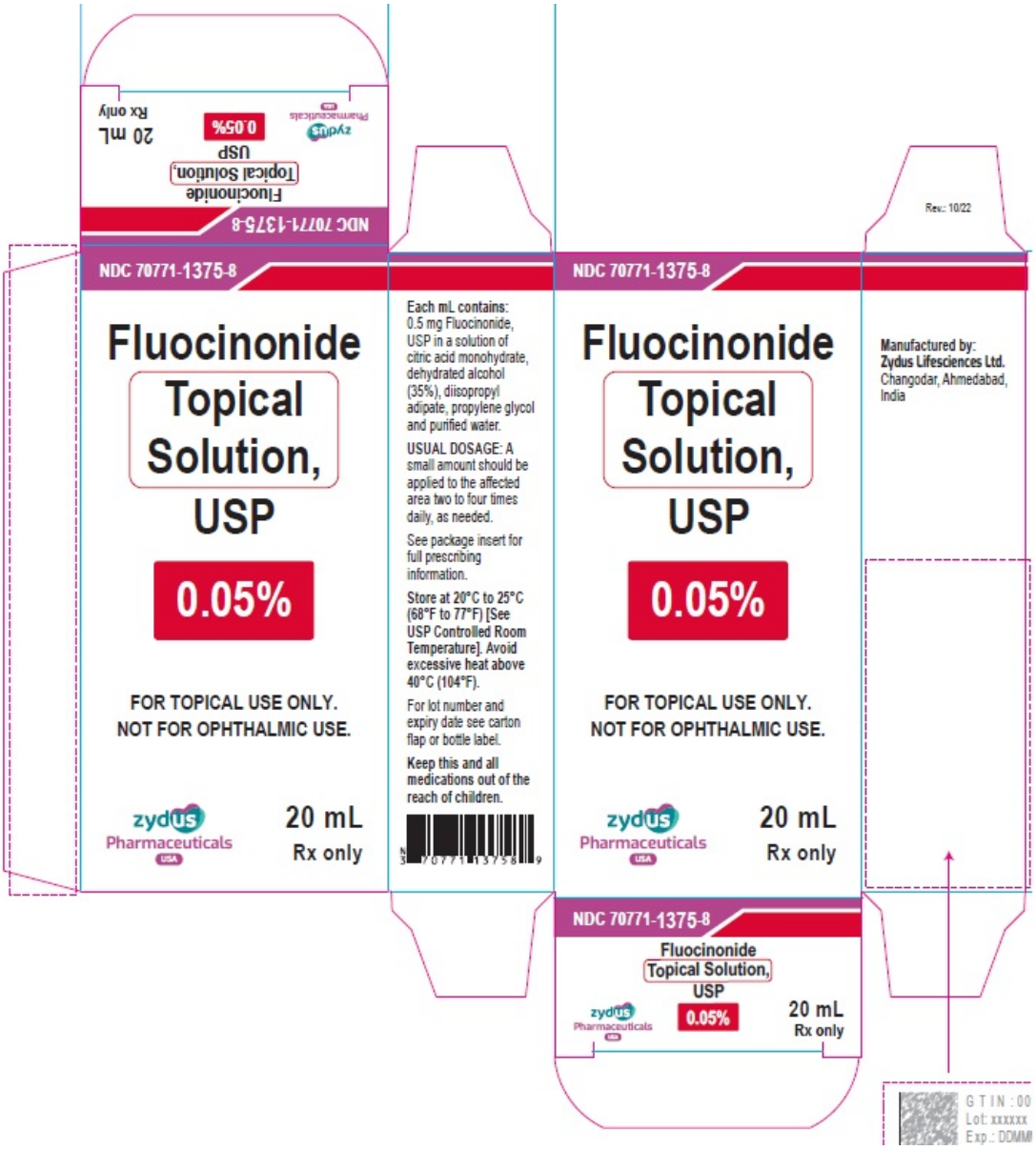
For lot number and expiry date see carton flap or bottle label.

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

Manufactured by:
Zydus Lifesciences Ltd.
Changodar, Ahmedabad, India

N 3 70771 13758 9

Back Label



FLUOCINONIDE

fluocinonide solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1375
Route of Administration	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: 059QF0KO0R)	

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 - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (650650802)

Establishment

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

Revised: 11/2024 Zydus Lifesciences Limited