

**FLUOCINONIDE - fluocinonide cream**  
**Zydus Lifesciences Limited**

**FLUOCINONIDE CREAM**

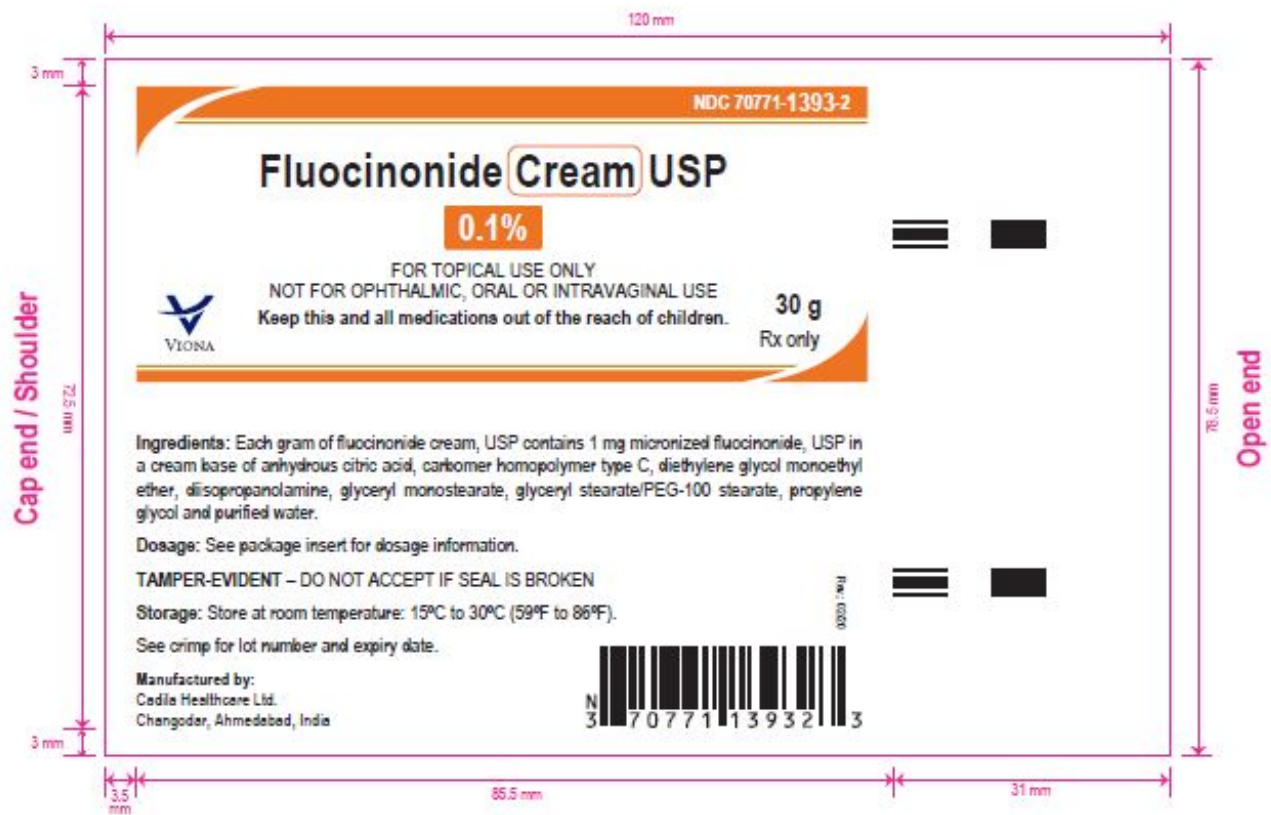
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

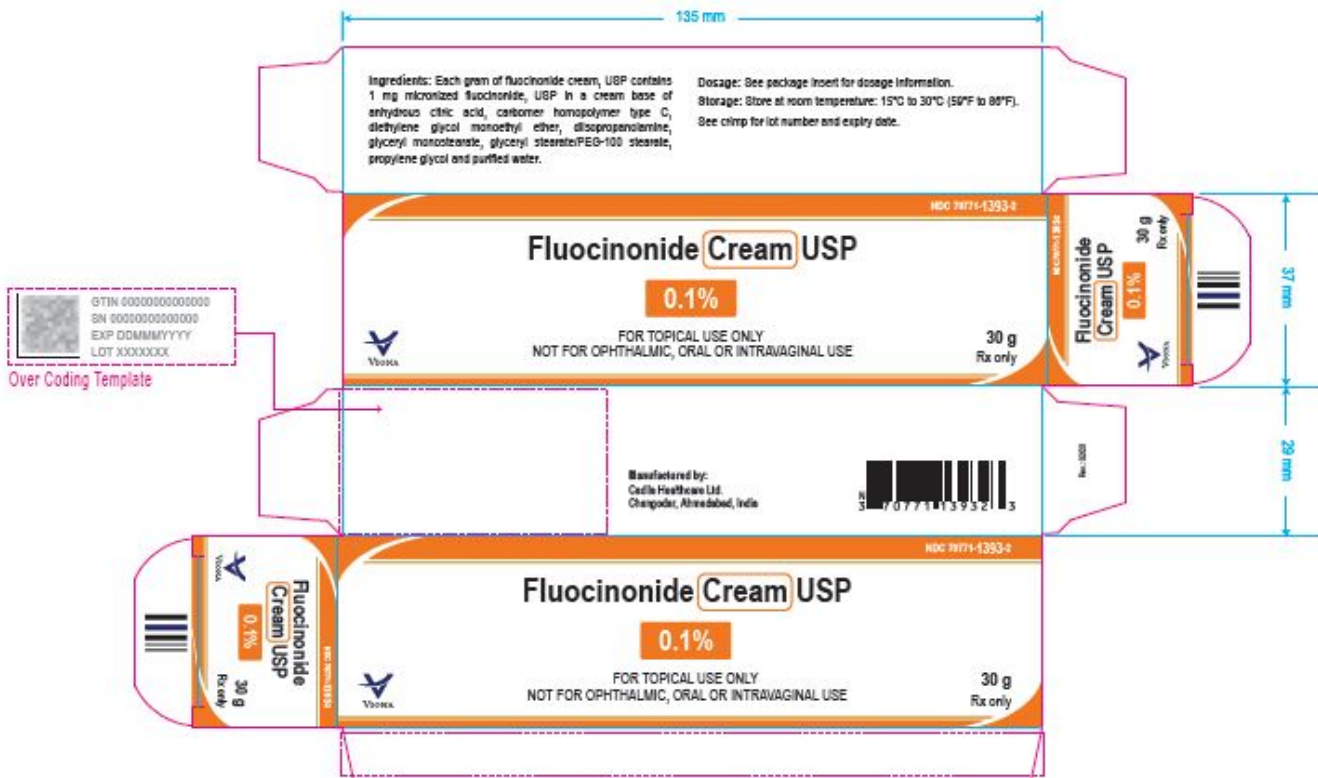
NDC 70771-1393-2

Fluocinonide Cream USP, 0.1%

Rx only

30 g





## FLUOCINONIDE

fluocinonide cream

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1393
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FLUOCINONIDE</b> (UNII: 2W4A77YPAN) (FLUOCINONIDE - UNII:2W4A77YPAN)	FLUOCINONIDE	1 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>CARBOMER HOMOPOLYMER TYPE C</b> (UNII: 4Q93RCW27E)	
<b>DIETHYLENE GLYCOL MONOETHYL ETHER</b> (UNII: A1A18X02B)	
<b>DIISOPROPANOLAMINE</b> (UNII: 0W44HYL8T5)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	WHITE (white to off-white)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1393-2	30 g in 1 TUBE; Type 0: Not a Combination Product	04/30/2020	
2	NDC:70771-1393-3	60 g in 1 TUBE; Type 0: Not a Combination Product	04/30/2020	
3	NDC:70771-1393-5	120 g in 1 TUBE; Type 0: Not a Combination Product	04/30/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208989	04/30/2020	

**Labeler** - Zydus Lifesciences Limited (918596198)

## Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650650802	ANALYSIS(70771-1393) , MANUFACTURE(70771-1393)

Revised: 11/2022

Zydus Lifesciences Limited