

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

The image shows the principal display panel for Fluocinonide Cream USP 0.1%. The panel features an orange header with the product name "Fluocinonide Cream USP" in black text, with "Cream" highlighted in a rounded rectangle. Below the name, the concentration "0.1%" is displayed in white text on an orange background. To the left is the VIONA logo, and to the right is the quantity "30 g" and "Rx only". The text "FOR TOPICAL USE ONLY" and "NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE" is centered, followed by the warning "Keep this and all medications out of the reach of children." Below this, the ingredients, dosage, and storage information are provided. A barcode is located at the bottom center, with the number "N 317257810870617" printed below it. The text "Rev: 0824" is printed vertically on the right side of the panel. Two sets of pink and black horizontal lines are positioned on the right side of the panel.

Fluocinonide Cream USP
0.1%
FOR TOPICAL USE ONLY
NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE
Keep this and all medications out of the reach of children.
30 g
Rx only
VIONA

Ingredients: Each gram of fluocinonide cream, USP contains 1 mg micronized fluocinonide, USP in a cream base of anhydrous citric acid, carbomer homopolymer type C, diethylene glycol monoethyl ether, diisopropanolamine, glyceryl monostearate, glyceryl stearate/PEG-100 stearate, propylene glycol and purified water.

Dosage: See package insert for dosage information.

TAMPER-EVIDENT – DO NOT ACCEPT IF SEAL IS BROKEN

Storage: Store at room temperature: 15°C to 30°C (59°F to 86°F).
See crimp for lot number and expiry date.

Product of Italy
Manufactured by:
Zydus Lifesciences Ltd.
Changodar, Ahmedabad, India

Rev: 0824

N 317257810870617

FLUOCINONIDE

fluocinonide cream

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
DIISOPROPANOLAMINE (UNII: 0W44HYL8T5)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	WHITE (white to off-white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

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)

