

ACYCLOVIR - acyclovir cream
Zydus Lifesciences Limited

Acyclovir Cream, for topical use

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1808-5 in tube of 5 g

Acyclovir Cream, 5%

Rx only

2 g

The image shows the principal display panel for a 5g tube of Acyclovir Cream 5%. The panel features a green header with the NDC number 70771-1808-5. The product name 'Acyclovir Cream' is prominently displayed in the center, with '5%' in a green box below it. The VIONA logo is on the left, and the text 'For Topical Use', 'USE ONLY FOR COLD SORES', and 'Keep this and all medications out of the reach of children.' is centered. The quantity '5 g' and 'Rx only' are on the right. Below the header, there are two sets of horizontal lines and a black square, likely representing the crimped end of the tube. The bottom section contains usage instructions, storage conditions, and a barcode with the number (01)00370771180851. Manufacturing information 'Made in India', 'GUJ/DRUGS/25/1919', and 'Rev.: 03/23' is also present.

NDC 70771-1808-5

Acyclovir Cream
5%

For Topical Use
USE ONLY FOR COLD SORES
Keep this and all medications out of the reach of children.

VIONA

5 g
Rx only

Each gram contains 50 mg acyclovir, USP
Usual dosage: Apply 5 times per day for 4 days. See package insert for full prescribing information.
Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (between 59°F and 86°F) [see USP Controlled Room Temperature].
SEE CRIMP FOR LOT NO. AND EXPIRATION DATE. FILLED BY WEIGHT, NOT BY VOLUME.

Made in India
GUJ/DRUGS/25/1919
Rev.: 03/23

(01)00370771180851



ACYCLOVIR

acyclovir cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1808
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACYCLOVIR (UNII: X4HES1O11F) (ACYCLOVIR - UNII:X4HES1O11F)	ACYCLOVIR	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
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:70771-1808-2	1 in 1 CARTON	03/03/2023	
1		2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:70771-1808-5	1 in 1 CARTON	03/03/2023	
2		5 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	ANDA206770	03/03/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650650802	ANALYSIS(70771-1808) , MANUFACTURE(70771-1808)

Revised: 3/2023

Zydus Lifesciences Limited