

**CLOBETASOL PROPIONATE - clobetasol propionate cream**  
**Zydus Lifesciences Limited**

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**Clobetasol Propionate Cream USP, 0.05%**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1442-1

Clobetasol Propionate Cream USP, 0.05%

Rx only

15 g

The image shows the principal display panel for Clobetasol Propionate Cream USP, 0.05%. The panel features a purple and pink header with the NDC number 70771-1442-1. The product name 'Clobetasol Propionate Cream, USP' is prominently displayed, with 'Cream' in a pink box. Below the name, the concentration '0.05%' is shown in a pink box. The Zydus Pharmaceuticals logo is on the left, and the text 'For dermatologic use only Not for ophthalmic use.' is in the center. The weight '15 g' and 'Rx only' are on the right. A barcode is at the bottom, with the number 'N 3 70771 14421 1' below it. Two sets of pink horizontal lines and black squares are on the right side of the panel.

**NDC 70771-1442-1**

**Clobetasol Propionate **Cream**, USP**

**0.05%**

**zydus**  
pharmaceuticals

For dermatologic use only  
Not for ophthalmic use.

15 g  
Rx only

Each gram contains: 0.5 mg clobetasol propionate, USP in a cream base composed of propylene glycol, cetyl alcohol, stearyl alcohol, citric acid monohydrate, sodium citrate anhydrous, methylparaben, propylparaben, ethylene glycol stearate, PEG-400 monostearate, polysorbate 60, lanolin oil, white petrolatum, and purified water.  
Store between 15° and 30°C (59° and 86°F). Do not refrigerate.

**WARNING: Keep out of reach of children.**

**Usual Dosage:** See package insert for full prescribing information.  
See crimp for lot no. and expiration date.

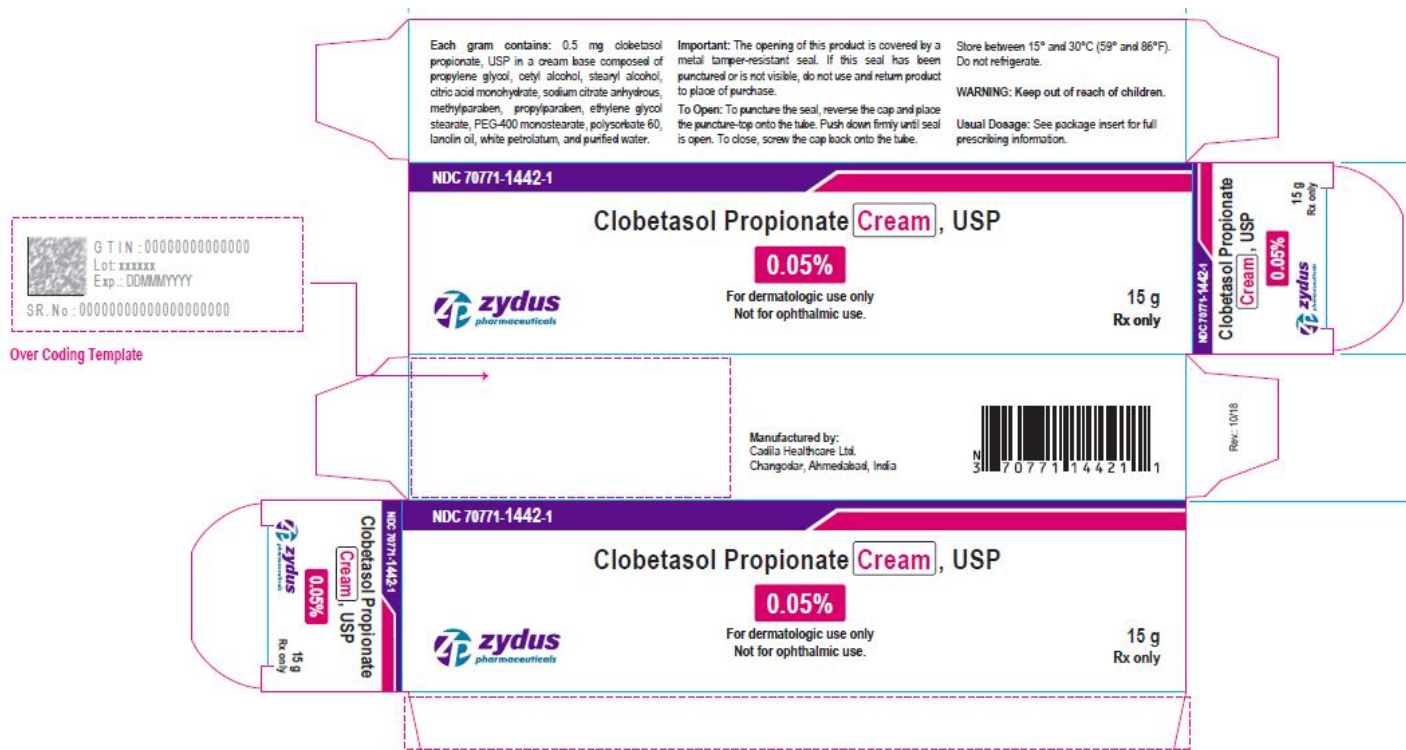
**Important:** Do not use if seal has been punctured or is not visible.

**To Open:** Use cap to puncture seal.

Manufactured by:  
Cadilla Healthcare Ltd.  
Changodar, Ahmedabad, India

Rev: 10/18

N 3 70771 14421 1



## CLOBETASOL PROPIONATE

clobetasol propionate cream

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1442
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CLOBETASOL PROPIONATE</b> (UNII: 779619577M) (CLOBETASOL - UNII:ADN79D536H)	CLOBETASOL PROPIONATE	0.5 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>ANHYDROUS TRISODIUM CITRATE</b> (UNII: RS7A450LGA)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>LANOLIN OIL</b> (UNII: OVV5IJ58F)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>WATER</b> (UNII: 059QF0KO0R)	

GLYCOL STEARATE (UNII: 0324G66D0E)

PEG-8 STEARATE (UNII: 2P9L47VI5E)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1442-1	1 in 1 CARTON	01/09/2019	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:70771-1442-2	1 in 1 CARTON	01/09/2019	
2		30 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:70771-1442-4	1 in 1 CARTON	01/09/2019	
3		45 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:70771-1442-3	1 in 1 CARTON	01/09/2019	
4		60 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	ANDA211074	01/09/2019	

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

**Registrant** - Zydus Lifesciences Limited (650650802)

### Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650650802	ANALYSIS(70771-1442) , MANUFACTURE(70771-1442)

Revised: 10/2022

Zydus Lifesciences Limited