

CLOBETASOL PROPIONATE - clobetasol propionate spray
Zydus Lifesciences Limited

Clobetasol Propionate Spray, 0.05%

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NDC 70771-1080-6

2 fl. oz. (59 mL)

The image shows a rectangular product label with a purple and blue color scheme. At the top left, there is a barcode with the number '3N' above it and '707711108060' below it. To the right of the barcode, the NDC number 'NDC 70771-1080-6' is printed in white on a purple background. The main text in the center reads 'Clobetasol Propionate' in large black font, followed by 'SPRAY' in a smaller black font, and '0.05%' in white text inside a blue rounded rectangle. Below this, it says 'For topical use only'. At the bottom left is the Zydus logo. At the bottom right, it lists the volume '2 fl. oz. (59 mL)' and 'Rx only'. On the far right, there is a vertical line of text: 'Rev. 07/17', 'CAD091/032519-9', and 'Made in India'. The label also contains detailed usage instructions, a warning about flammability, and storage information.

NDC 70771-1080-6

Clobetasol Propionate
SPRAY
0.05%

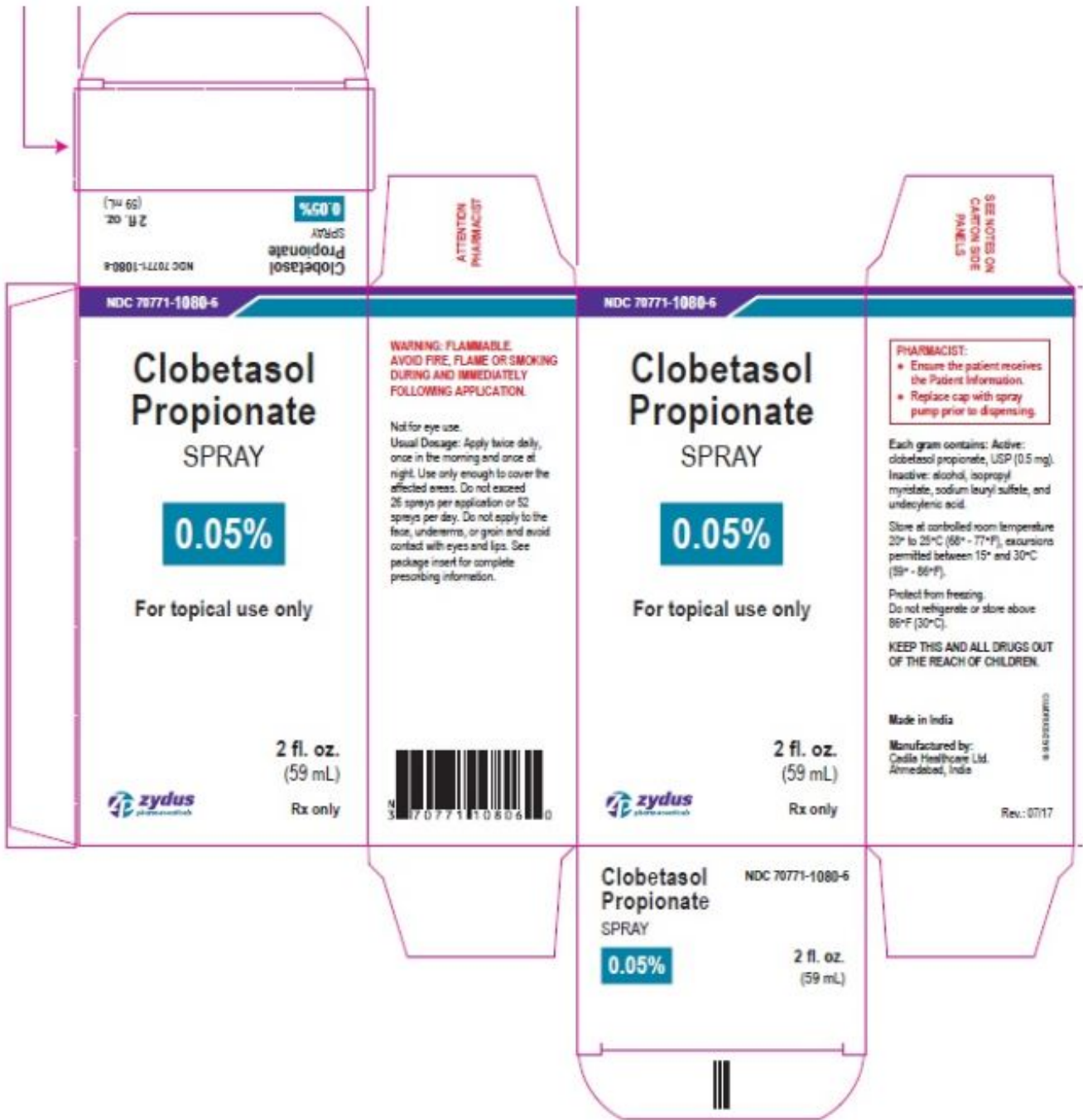
For topical use only

2 fl. oz.
(59 mL)
Rx only

zydus
pharmaceuticals

Not for eye use.
Usual Dosage: Apply twice daily, once in the morning and once at night. Use only enough to cover the affected areas. Do not exceed 26 sprays per application or 52 sprays per day. Do not apply to the face, underarms, or groin and avoid contact with eyes and lips. See package insert for complete prescribing information.
Each gram contains: Active: clobetasol propionate, USP (0.5 mg). Inactive: alcohol, isopropyl myristate, sodium lauryl sulfate, and undecylenic acid.
Store at controlled room temperature 20° to 25°C (68° - 77°F), excursions permitted between 15° and 30°C (59° - 86°F).
Protect from freezing.
Do not refrigerate or store above 86°F (30°C).
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
WARNING: FLAMMABLE. AVOID FIRE, FLAME OR SMOKING DURING AND IMMEDIATELY FOLLOWING APPLICATION.

Rev. 07/17
CAD091/032519-9
Made in India
Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India



Clobetasol Propionate Spray, 0.05%

NDC 70771-1080-7

4.25 fl. oz. (125 mL)

NDC 70771-1080-7



Clobetasol Propionate

SPRAY

0.05%

For topical use only

4.25 fl. oz.
(125 mL)

Rx only



Not for eye use.

Usual Dosage: Apply twice daily, once in the morning and once at night. Use only enough to cover the affected areas. Do not exceed 26 sprays per application or 52 sprays per day. Do not apply to the face, underarms, or groin and avoid contact with eyes and lips. See package insert for complete prescribing information.

Each gram contains: Active: clobetasol propionate, USP (0.5 mg). Inactive: alcohol, isopropyl myristate, sodium lauryl sulfate, and undecylenic acid.

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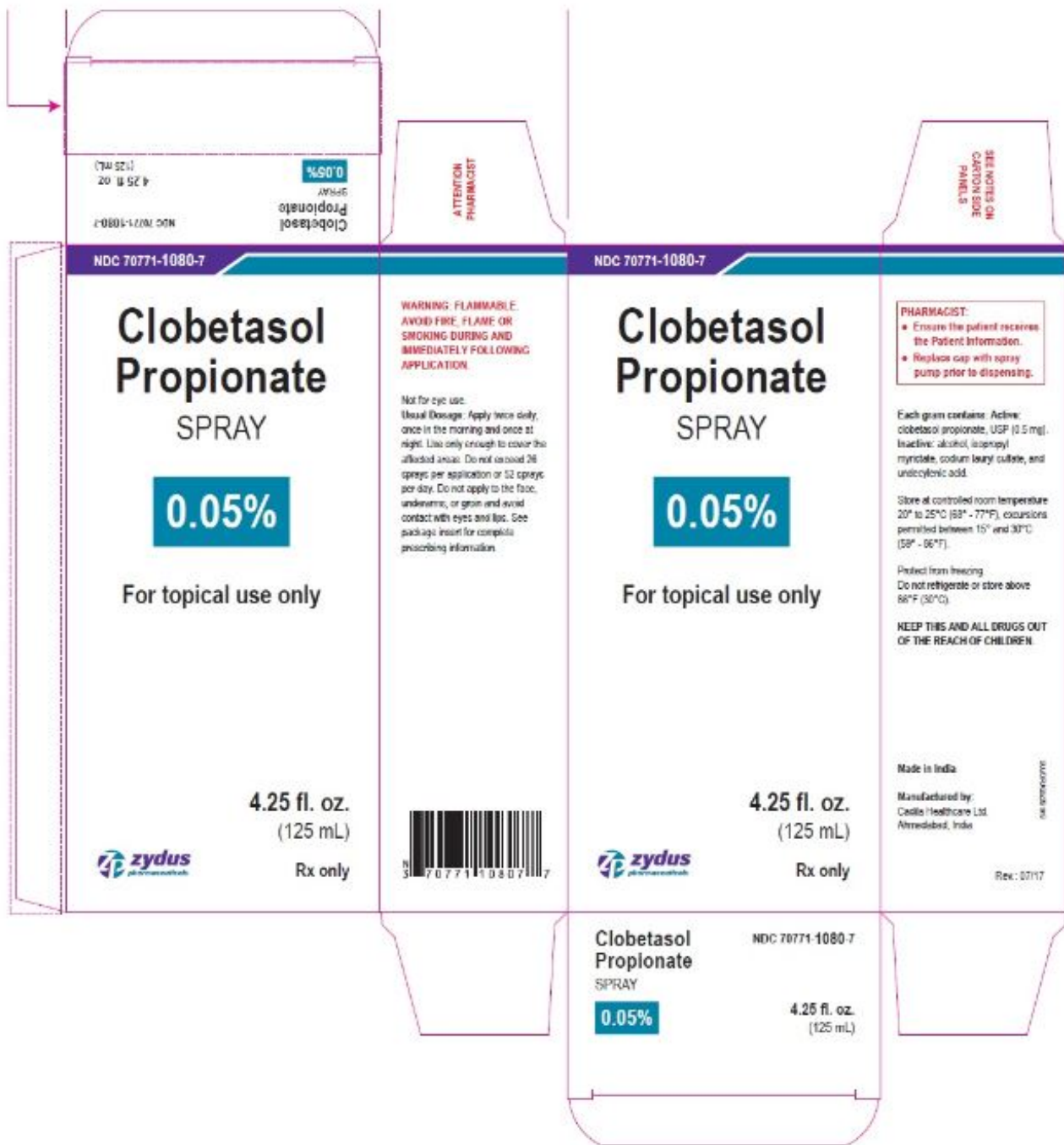
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

WARNING: FLAMMABLE. AVOID FIRE, FLAME OR SMOKING DURING AND IMMEDIATELY FOLLOWING APPLICATION.

Made in India

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

61615210/00170
01/01/2016



CLOBETASOL PROPIONATE

clobetasol propionate spray

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOBETASOL PROPIONATE (UNII: 779619577M) (CLOBETASOL -	CLOBETASOL	0.05 g

UNII:ADN79D536H)		PROPIONATE	in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ALCOHOL (UNII: 3K9958V90M)				
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
UNDECYLENIC ACID (UNII: K3D86KJ24N)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1080-7	1 in 1 CARTON	07/12/2017	
1		125 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70771-1080-6	1 in 1 CARTON	07/12/2017	
2		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA206378		07/12/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650650802	ANALYSIS(70771-1080) , MANUFACTURE(70771-1080)

Revised: 10/2022

Zydus Lifesciences Limited