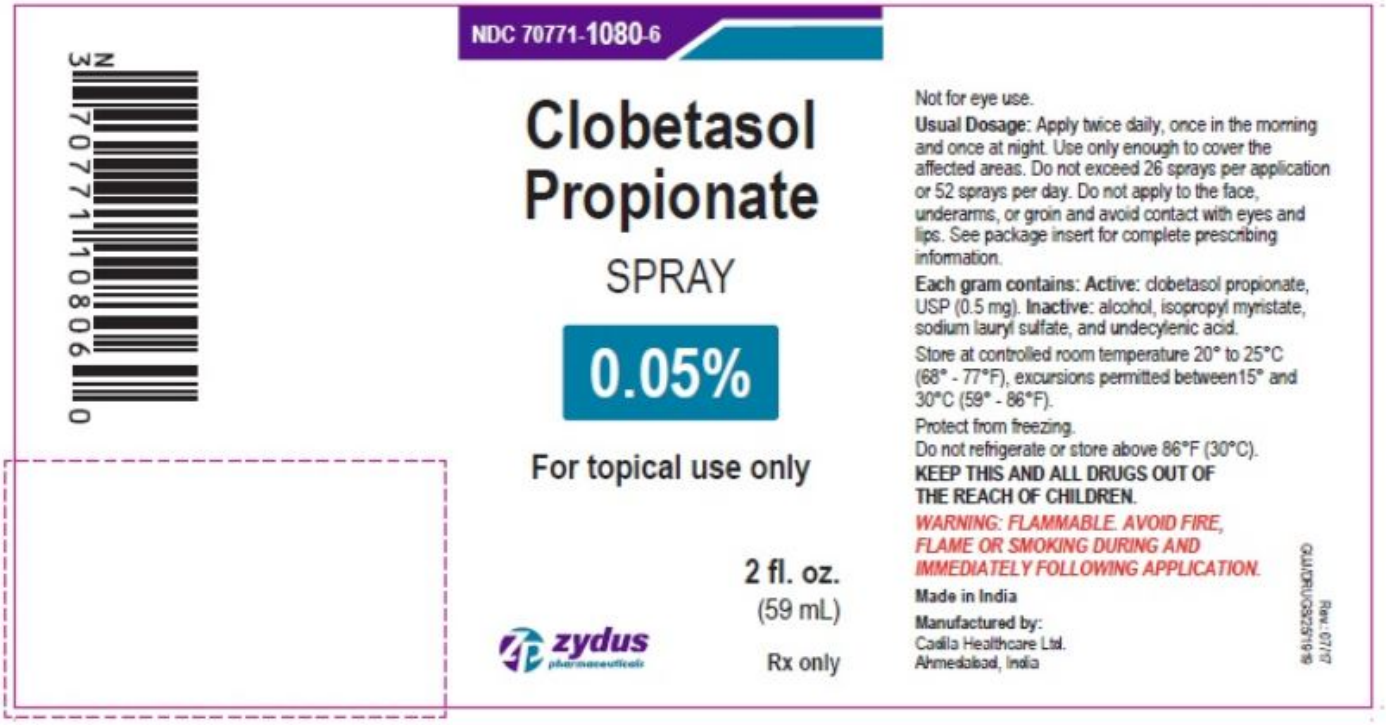
CLOBETASOL PROPIONATE - clobetasol propionate spray
Zydus Lifesciences Limited

Clobetasol Propionate Spray, 0.05%

Clobetasol Propinate Spray, 0.05%

NDC 70771-1080-6

2 fl. oz. (59 mL)



Clobetasol Propinate 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.

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).

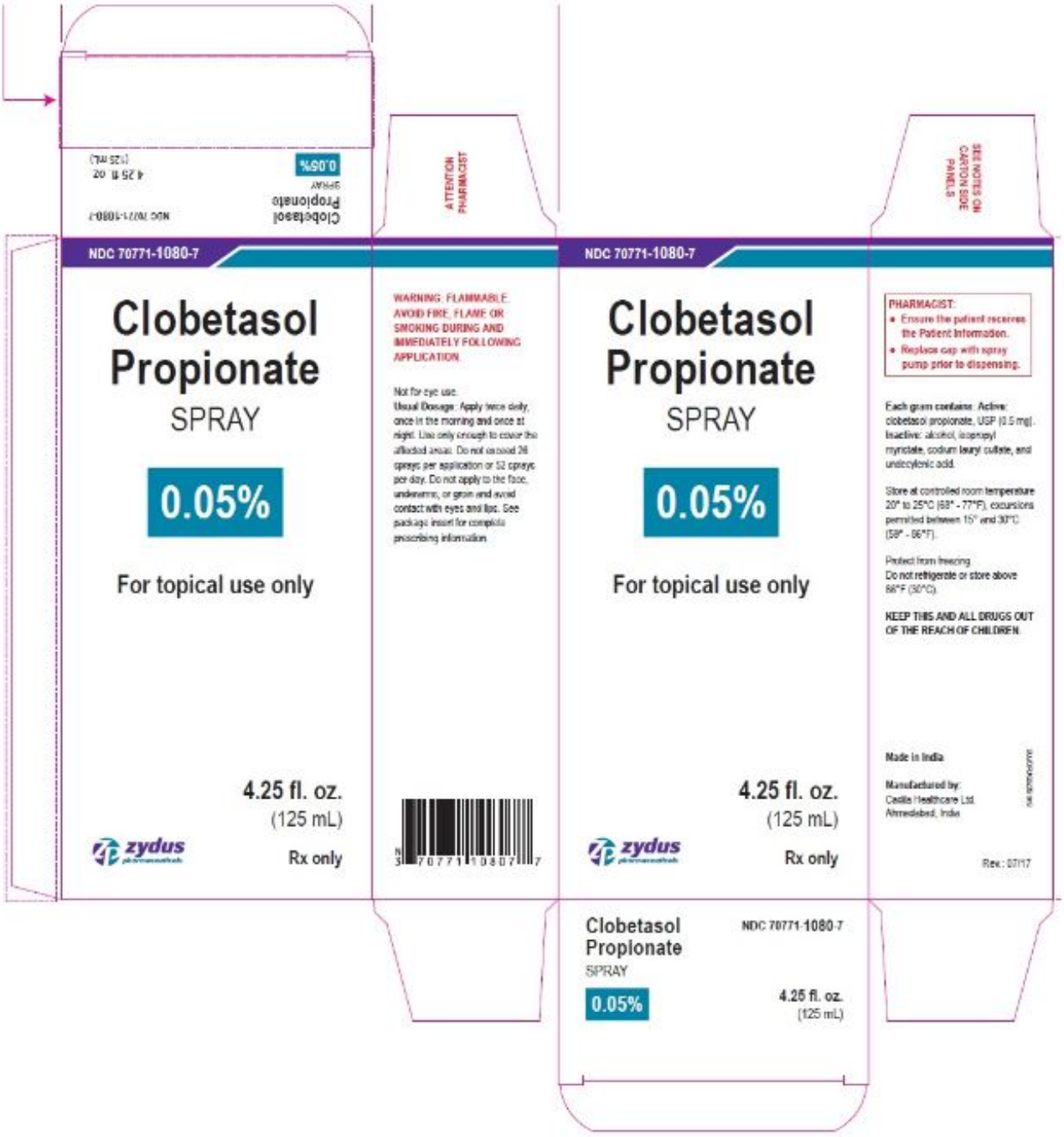
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

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

Made in India

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev. 07/17



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