

METRONIDAZOLE- metronidazole cream
Zydus Lifesciences Limited

Metronidazole Topical Cream, 0.75%

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1834-4

Metronidazole Topical Cream, 0.75%

Rx only

45 g

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Metronidazole Topical Cream

0.75%

45 g
Rx only

VIONA

FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC USE.

Each gram contains: **Active Ingredient** metronidazole, USP 0.75% (7.5 mg).
Inactive Ingredient benzyl alcohol, emulsifying wax, glycerin, isopropyl palmitate, purified water, sorbitol solution, lactic acid and sodium hydroxide to adjust pH.

Usual dosage: Apply a thin layer to entire affected areas after washing. Use morning and evening or as directed by physician. Avoid application close to the eyes.

Keep this and all drugs out of the reach of children.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F)
[See USP Controlled Room Temperature].

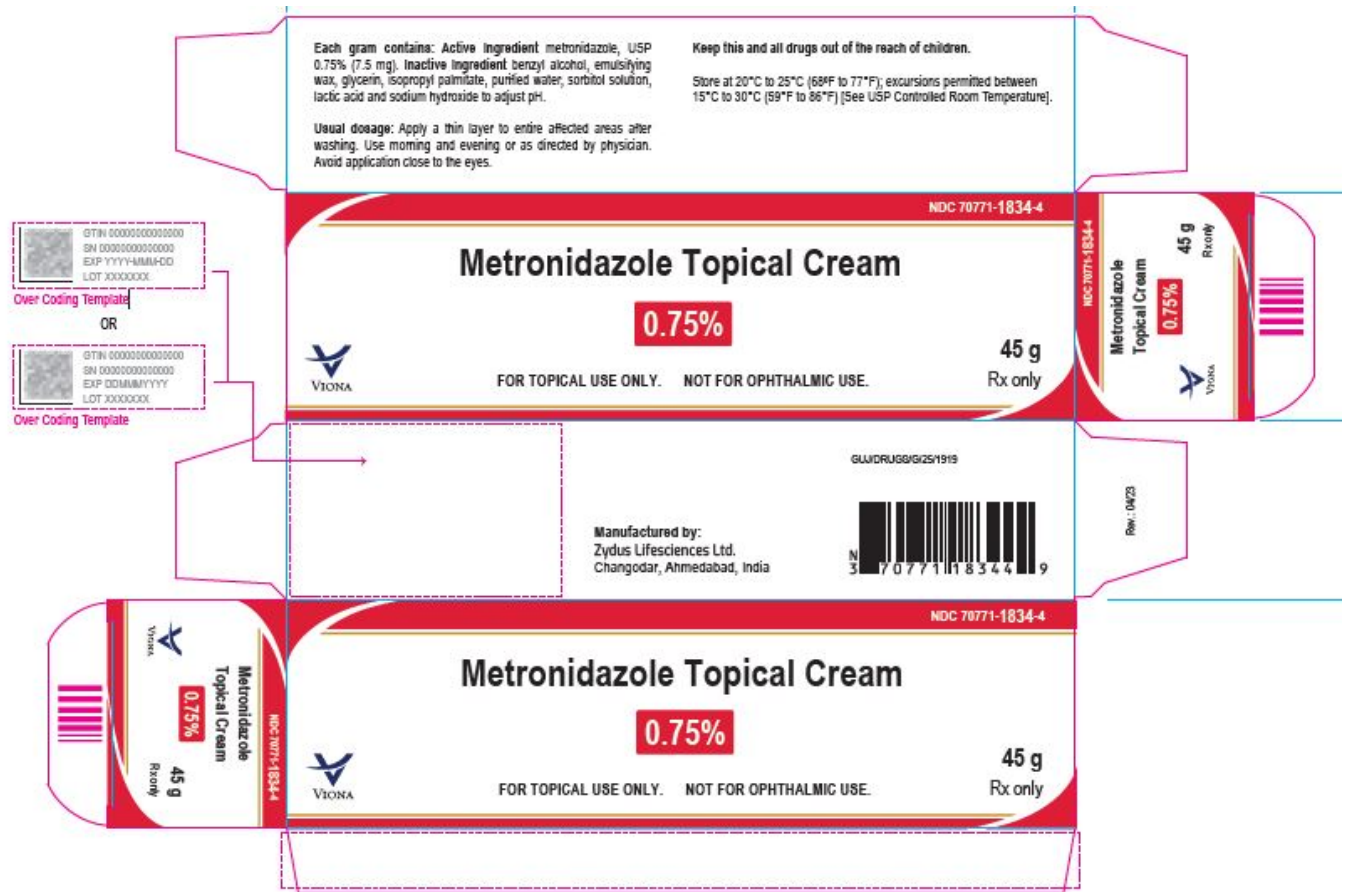
See crimp of tube for lot number and expiration date.

GUJDRUGS/G/25/1919

Manufactured by:
Zydus Lifesciences Ltd.
Changodar, Ahmedabad, India

Rev: 04/23

370771183449



METRONIDAZOLE

metronidazole cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1834
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METRONIDAZOLE (UNII: 140QMO216E) (METRONIDAZOLE - UNII:140QMO216E)	METRONIDAZOLE	7.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
LACTIC ACID (UNII: 33X04XA5AT)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1834-4	1 in 1 CARTON	05/31/2023	
1		45 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	ANDA217128	05/31/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650650802	ANALYSIS(70771-1834) , MANUFACTURE(70771-1834)

Revised: 5/2023

Zydus Lifesciences Limited