

CLOBAZAM- clobazam tablet
Zydus Lifesciences Limited

CLOBAZAM TABLETS

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

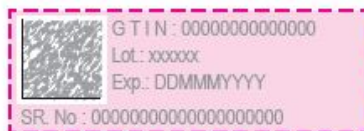
NDC 70771-1440-1

Clobazam Tablets, 10 mg

100 Tablets

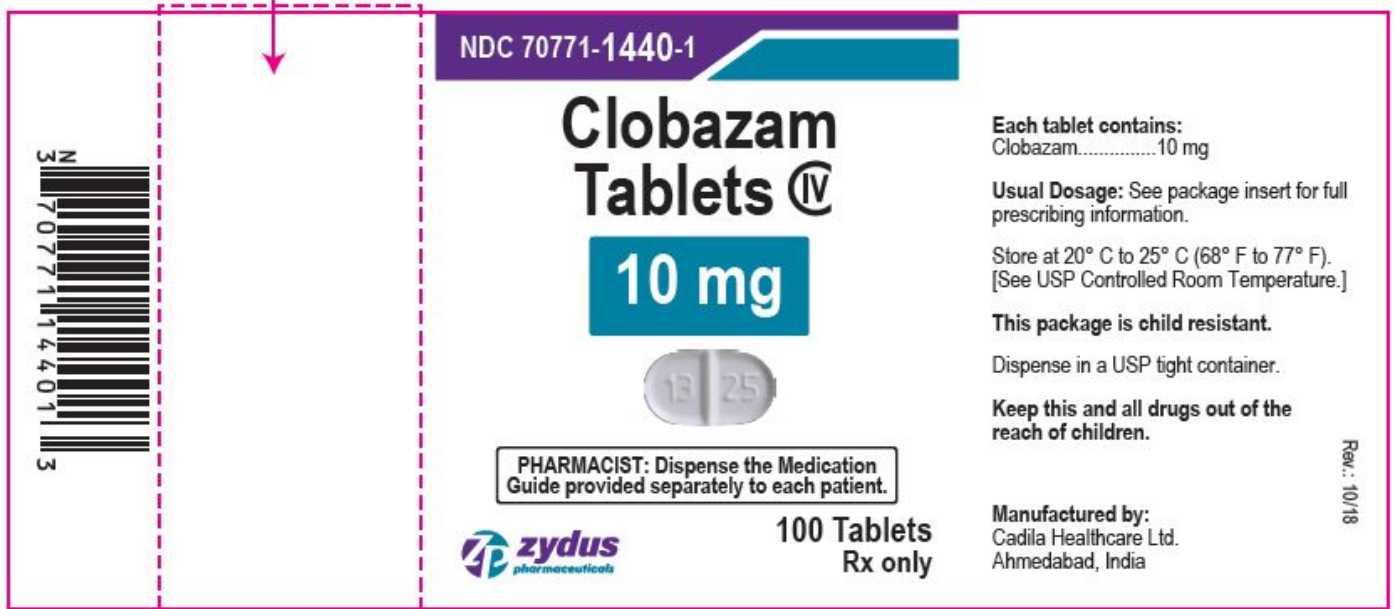
Rx only

Zydus



Over Coding Template

No Varnished Area (Do Not Print)
(18 x 41 mm)



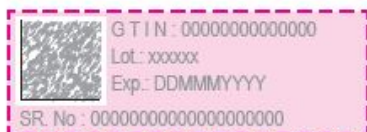
NDC 70771-1441-1

Clobazam Tablets, 20 mg

100 Tablets

Rx only

Zydus



Over Coding Template

No Varnished Area (Do Not Print)
(18 x 41 mm)

NDC 70771-1441-1

**Clobazam
Tablets [Ⓢ]**

20 mg

13 26

**PHARMACIST: Dispense the Medication
Guide provided separately to each patient.**

**zydus
pharmaceuticals**

**100 Tablets
Rx only**

**Each tablet contains:
Clobazam.....20 mg**

Usual Dosage: See package insert for full
prescribing information.

Store at 20° C to 25° C (68° F to 77° F).
[See USP Controlled Room Temperature.]

This package is child resistant.

Dispense in a USP tight container.

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

**Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India**

Rev: 10/18

CLOBAZAM

clobazam tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1440
Route of Administration	ORAL	DEA Schedule	CIV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOBAZAM (UNII: 2MRO291B4U) (CLOBAZAM - UNII:2MRO291B4U)	CLOBAZAM	10 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	WHITE (OFF-WHITE)	Score	2 pieces
Shape	CAPSULE (MODIFIED CAPSULE)	Size	9mm
Flavor		Imprint Code	13;25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1440-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/22/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211449	10/22/2018	

CLOBAZAM

clobazam tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1441
Route of Administration	ORAL	DEA Schedule	CIV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOBAZAM (UNII: 2MRO291B4U) (CLOBAZAM - UNII:2MRO291B4U)	CLOBAZAM	20 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	WHITE (OFF-WHITE)	Score	2 pieces
Shape	CAPSULE (MODIFIED CAPSULE)	Size	11mm
Flavor		Imprint Code	13;26
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1441-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/22/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211449	10/22/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (863362789)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1440, 70771-1441) , MANUFACTURE(70771-1440, 70771-1441)

Revised: 9/2023

Zydus Lifesciences Limited