

TRIAZOLAM- triazolam tablet
Zydus Lifesciences Limited

Triazolam Tablets, USP CIV

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1576-8

Triazolam Tablets USP, 0.125 mg

10 Tablets

Rx only

NDC 70771-1576-8

**Triazolam
Tablets, USP [Ⓒ]IV**

0.125 mg

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

10 Tablets
Rx only

Each tablet contains 0.125 mg triazolam, USP.
Usual Dosage: See package insert for full prescribing information.
This package is child-resistant.
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].
Dispense in a tight, light-resistant container as defined in the USP.
Keep this and all drugs out of the reach of children.
Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.
Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 12/22

NDC 70771-1162- 8

Triazolam Tablets USP, 0.25 mg

10 Tablets

Rx only

NDC 70771-1162-8



Rev.: 12/22

Triazolam Tablets, USP [Ⓢ]

0.25 mg

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



Each tablet contains 0.25 mg triazolam, USP.
Usual Dosage: See package insert for full prescribing information.
 This package is child-resistant.
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].
 Dispense in a tight, light-resistant container as defined in the USP.
 Keep this and all drugs out of the reach of children.
 Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.
Manufactured by:
 Cadila Healthcare Ltd.
 Ahmedabad, India

10 Tablets
Rx only

TRIAZOLAM

triazolam tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1162
Route of Administration	ORAL	DEA Schedule	CIV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRIAZOLAM (UNII: 1HM943223R) (TRIAZOLAM - UNII:1HM943223R)	TRIAZOLAM	0.25 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	GRAY (light-grayish blue)	Score	2 pieces
Shape	OVAL (elliptical)	Size	8mm
Flavor		Imprint Code	12;89
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1162-8	10 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2022	
2	NDC:70771-1162-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2022	
3	NDC:70771-1162-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213003	12/30/2022	

TRIAZOLAM

triazolam tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1576
Route of Administration	ORAL	DEA Schedule	CIV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRIAZOLAM (UNII: 1HM943223R) (TRIAZOLAM - UNII:1HM943223R)	TRIAZOLAM	0.125 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (off-white)	Score	no score
Shape	OVAL (elliptical)	Size	8mm
Flavor		Imprint Code	1521
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1576-8	10 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2022	
2	NDC:70771-1576-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2022	
3	NDC:70771-1576-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213003	12/30/2022	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1576, 70771-1162) , MANUFACTURE(70771-1576, 70771-1162)

Revised: 9/2023

Zydus Lifesciences Limited