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

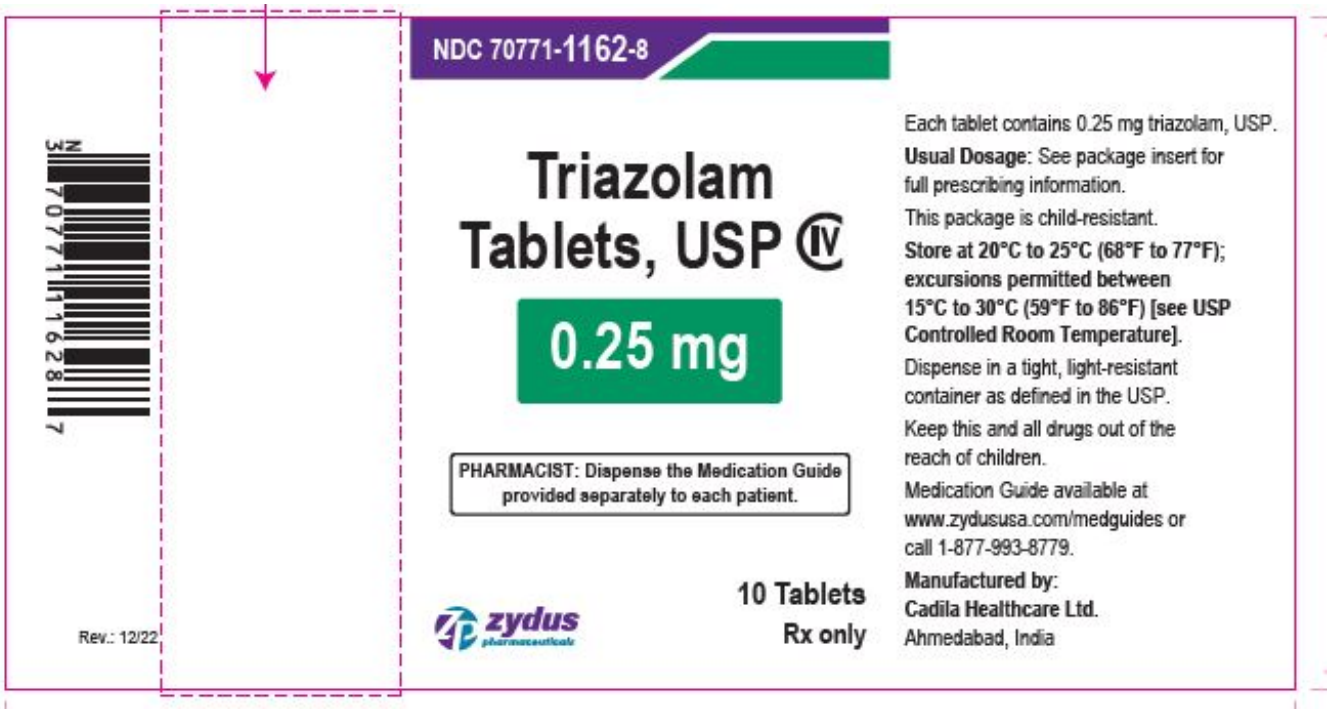
Rx only

NDC 70771-1162- 8

Triazolam Tablets USP, 0.25 mg

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