TRAZODONE HYDROCHLORIDE - trazodone hydrochloride tablet
Zydus Lifesciences Limited

TRAZODONE HYDROCHLORIDE TABLETS

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1128-1

Trazodone Hydrochloride Tablets USP, 50 mg

100 Tablets

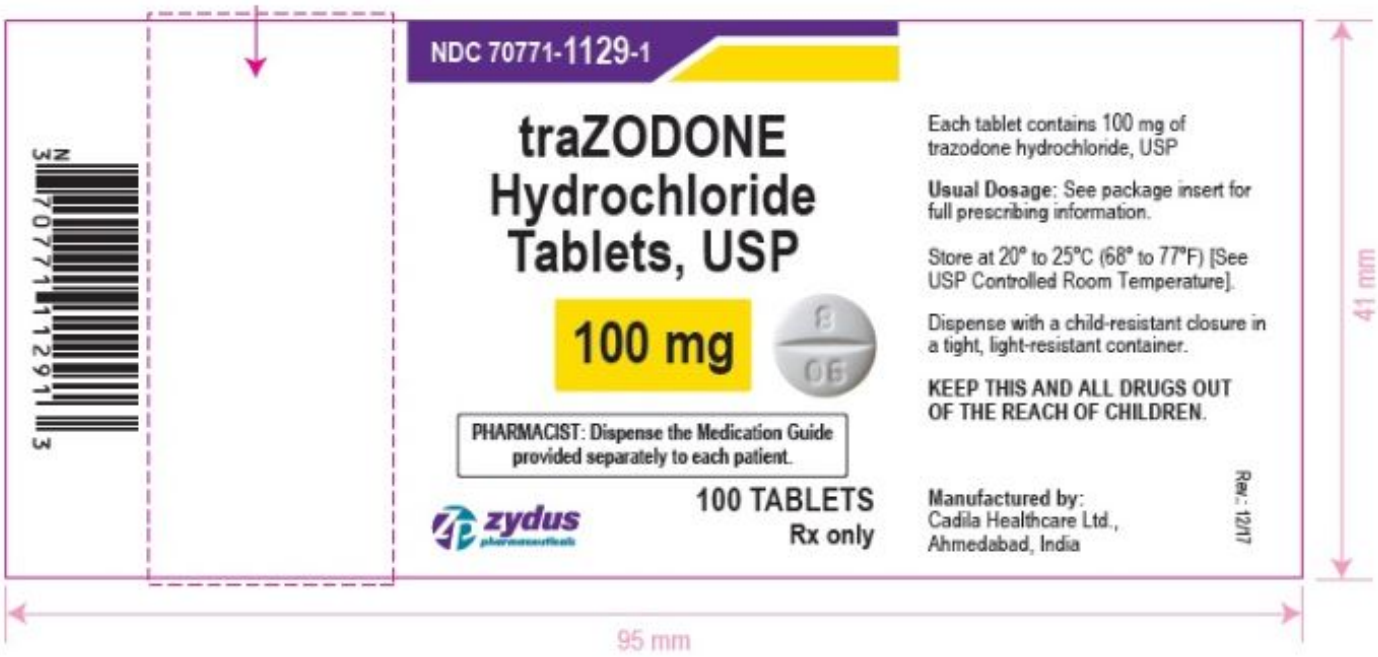
Rx only

NDC 70771-1129-1

Trazodone Hydrochloride Tablets USP, 100 mg

100 Tablets

Rx only

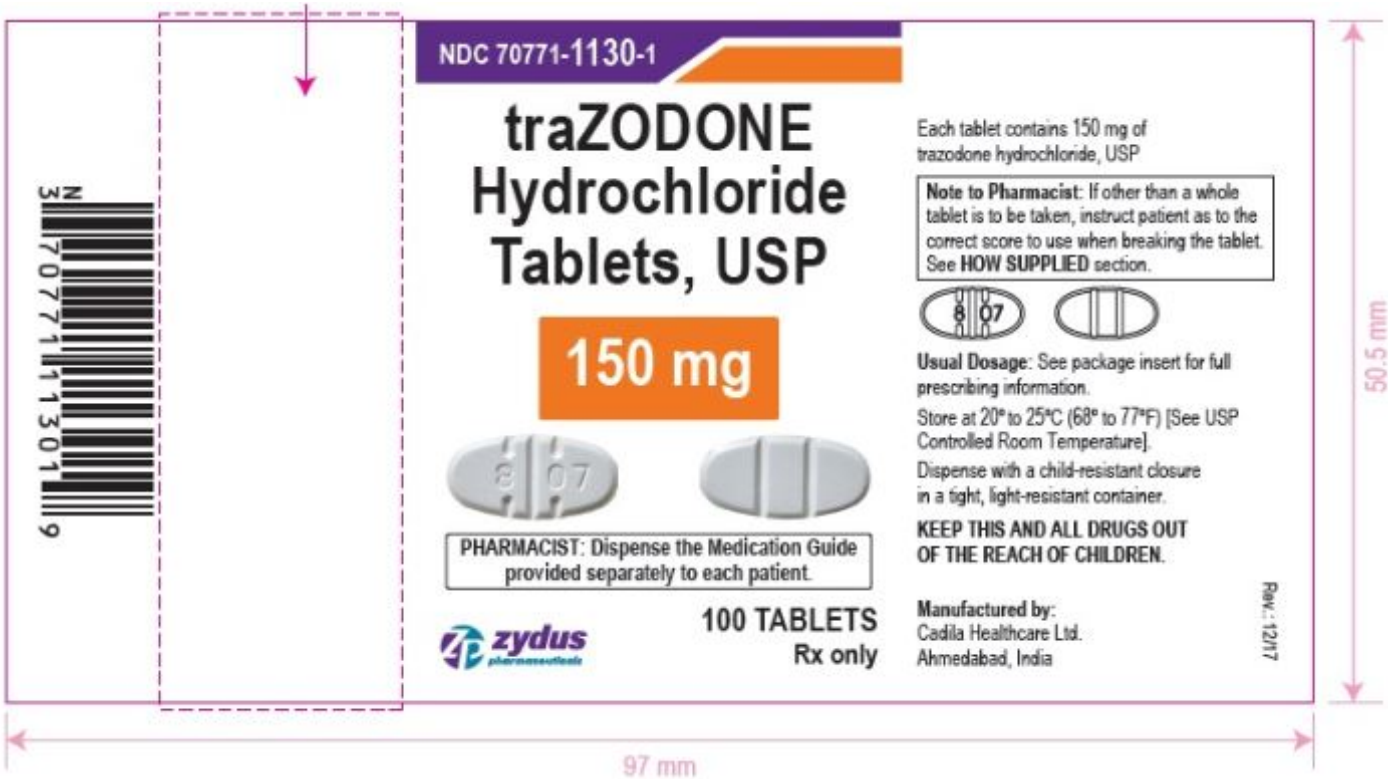


NDC 70771-1130-1

Trazodone Hydrochloride Tablets USP, 150 mg

100 Tablets

Rx only



NDC 70771-1131-1

Trazodone Hydrochloride Tablets USP, 300 mg

100 Tablets

Rx only

TRAZODONE HYDROCHLORIDE

trazodone hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1128
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRAZODONE HYDROCHLORIDE (UNII: 6E8ZO8LRNM) (TRAZODONE - UNII:YBK48BXK30)	TRAZODONE HYDROCHLORIDE	50 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	ROUND (ROUND)	**Size**	8mm
Flavor		**Imprint Code**	8;05
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1128-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
2	NDC:70771-1128-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
3	NDC:70771-1128-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
4	NDC:70771-1128-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
5	NDC:70771-1128-4	10 in 1 CARTON	12/11/2017	
5	NDC:70771-1128-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:70771-1128-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205253	12/11/2017	

TRAZODONE HYDROCHLORIDE

trazodone hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1129
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRAZODONE HYDROCHLORIDE (UNII: 6E8ZO8LRNM) (TRAZODONE - UNII:YBK48BXK30)	TRAZODONE HYDROCHLORIDE	100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	ROUND (ROUND)	**Size**	10mm
Flavor		**Imprint Code**	8;06
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1129-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
2	NDC:70771-1129-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
3	NDC:70771-1129-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
4	NDC:70771-1129-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
5	NDC:70771-1129-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
6	NDC:70771-1129-4	10 in 1 CARTON	12/11/2017	
6	NDC:70771-1129-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205253	12/11/2017	

TRAZODONE HYDROCHLORIDE

trazodone hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1130
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRAZODONE HYDROCHLORIDE (UNII: 6E8ZO8LRNM) (TRAZODONE - UNII:YBK48BXK30)	TRAZODONE HYDROCHLORIDE	150 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	3 pieces
Shape	OVAL (OVAL)	**Size**	17mm
Flavor		**Imprint Code**	8;07
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1130-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
2	NDC:70771-1130-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
3	NDC:70771-1130-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
4	NDC:70771-1130-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
5	NDC:70771-1130-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
6	NDC:70771-1130-4	10 in 1 CARTON	12/11/2017	
6	NDC:70771-1130-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205253	12/11/2017	

TRAZODONE HYDROCHLORIDE

trazodone hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1131
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRAZODONE HYDROCHLORIDE (UNII: 6E8ZO8LRNM) (TRAZODONE - UNII:YBK48BXK30)	TRAZODONE HYDROCHLORIDE	300 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	3 pieces
Shape	OVAL (OVAL)	**Size**	21mm
Flavor		**Imprint Code**	8;08
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1131-3	30 in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	12/11/2017	
2	NDC:70771-1131-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
3	NDC:70771-1131-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
4	NDC:70771-1131-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
5	NDC:70771-1131-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	
6	NDC:70771-1131-4	10 in 1 CARTON	12/11/2017	
6	NDC:70771-1131-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
ANDA	ANDA205253	12/11/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1128, 70771-1129, 70771-1130, 70771-1131) , MANUFACTURE(70771-1128, 70771-1129, 70771-1130, 70771-1131)

Revised: 10/2022 Zydus Lifesciences Limited