

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

3
N
683821806011
7

Rev.: 08/24

**traZODONE
Hydrochloride
Tablets, USP**

100 mg

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

zydus

**100 Tablets
Rx only**

Each tablet contains 100 mg of trazodone hydrochloride, USP
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].
 Dispense with a child-resistant closure in a tight, light-resistant container.
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.
Mfg. by: Zydus Lifesciences Ltd. India

NDC 70771-1130-1

Trazodone Hydrochloride Tablets USP, 150 mg

100 Tablets

Rx only

3
N
683821807011
4

Rev.: 08/24

**traZODONE
Hydrochloride
Tablets, USP**

150 mg

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

zydus

**100 Tablets
Rx only**

Each tablet contains 150 mg of trazodone hydrochloride, USP
Note to Pharmacist: If other than a whole tablet is to be taken, instruct patient as to the correct score to use when breaking the tablet. See HOW SUPPLIED section.



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].
 Dispense with a child-resistant closure in a tight, light-resistant container.
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.
Mfg. by: Zydus Lifesciences Ltd. India

NDC 70771-1131-1

Trazodone Hydrochloride Tablets USP, 300 mg

100 Tablets

Rx only

3 N
68382180801
1

Rev.: 08/24

traZODONE
Hydrochloride
Tablets, USP

300 mg

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

zydus

100 Tablets
Rx only

Each tablet contains 300 mg of
trazodone hydrochloride, USP

Note to Pharmacist: If other than a whole
tablet is to be taken, instruct patient as to the
correct score to use when breaking the tablet.
See **HOW SUPPLIED** section.

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].
Dispense with a child-resistant closure in a tight,
light-resistant container.
**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.
Mfg. by: Zydus Lifesciences Ltd.
India

NDC 70771-1938-1

Trazodone Hydrochloride Tablets USP, 50 mg

100 Tablets

Rx only

3 N
68382160901
4

Rev.: 01/26

traZODONE
Hydrochloride
Tablets, USP

50 mg

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

zydus

100 Tablets
Rx only

Each tablet contains 50 mg of
trazodone hydrochloride, USP

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].
Dispense with a child-resistant closure in
a tight, light-resistant container.
**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.
Mfg. by: Zydus Pharmaceuticals Ltd.
Ahmedabad, India

NDC 70771-1939-1

Trazodone Hydrochloride Tablets USP, 100 mg

100 Tablets

Rx only

3 N
683821 61001 0

traZODONE
Hydrochloride
Tablets, USP

100 mg

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

zydus

100 Tablets
Rx only

Each tablet contains 100 mg of trazodone hydrochloride, USP
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].
Dispense with a child-resistant closure in a tight, light-resistant container.
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.
Mfg. by: Zydus Pharmaceuticals Ltd.
Ahmedabad, India

Rev.: 01/26

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:70771-1128-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	12/31/2028
2	NDC:70771-1128-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	12/31/2028
3	NDC:70771-1128-4	10 in 1 CARTON	12/11/2017	12/31/2028
3	NDC:70771-1128-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:70771-1128-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	12/31/2028
5	NDC:70771-1128-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	12/31/2028
6	NDC:70771-1128-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	12/31/2028

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205253	12/11/2017	12/31/2028

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:70771-1129-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	12/31/2028
2	NDC:70771-1129-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	12/31/2028
3	NDC:70771-1129-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	12/31/2028
4	NDC:70771-1129-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	12/31/2028
5	NDC:70771-1129-4	10 in 1 CARTON	12/11/2017	12/31/2028
5	NDC:70771-1129-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:70771-1129-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2017	12/31/2028

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205253	12/11/2017	12/31/2028

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
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TRAZODONE HYDROCHLORIDE (UNII: 6E8ZO8LRNM) (TRAZODONE - UNII:YBK48BXK30)	TRAZODONE HYDROCHLORIDE	150 mg
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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 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:70771-1938
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	05
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1938-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/22/2026	
2	NDC:70771-1938-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/22/2026	
3	NDC:70771-1938-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/22/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205253	01/22/2026	

TRAZODONE HYDROCHLORIDE

trazodone hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1939
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	06
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1939-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/22/2026	
2	NDC:70771-1939-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/22/2026	
3	NDC:70771-1939-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/22/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205253	01/22/2026	

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)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		677605858	ANALYSIS(70771-1128, 70771-1129, 70771-1130, 70771-1131, 70771-1938, 70771-1939) , MANUFACTURE(70771-1128, 70771-1129, 70771-1130, 70771-1131, 70771-1938, 70771-1939)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Pharmaceuticals Limited		650173735	MANUFACTURE(70771-1130, 70771-1131, 70771-1938, 70771-1938) , ANALYSIS(70771-1130, 70771-1131, 70771-1938, 70771-1938)

Revised: 1/2026

Zydus Lifesciences Limited