LURASIDONE HYDROCHLORIDE- lurasidone hydrochloride tablet, coated
Zydus Lifesciences Limited

Lurasidone Hydrochloride Tablets

SPL MEDGUIDE

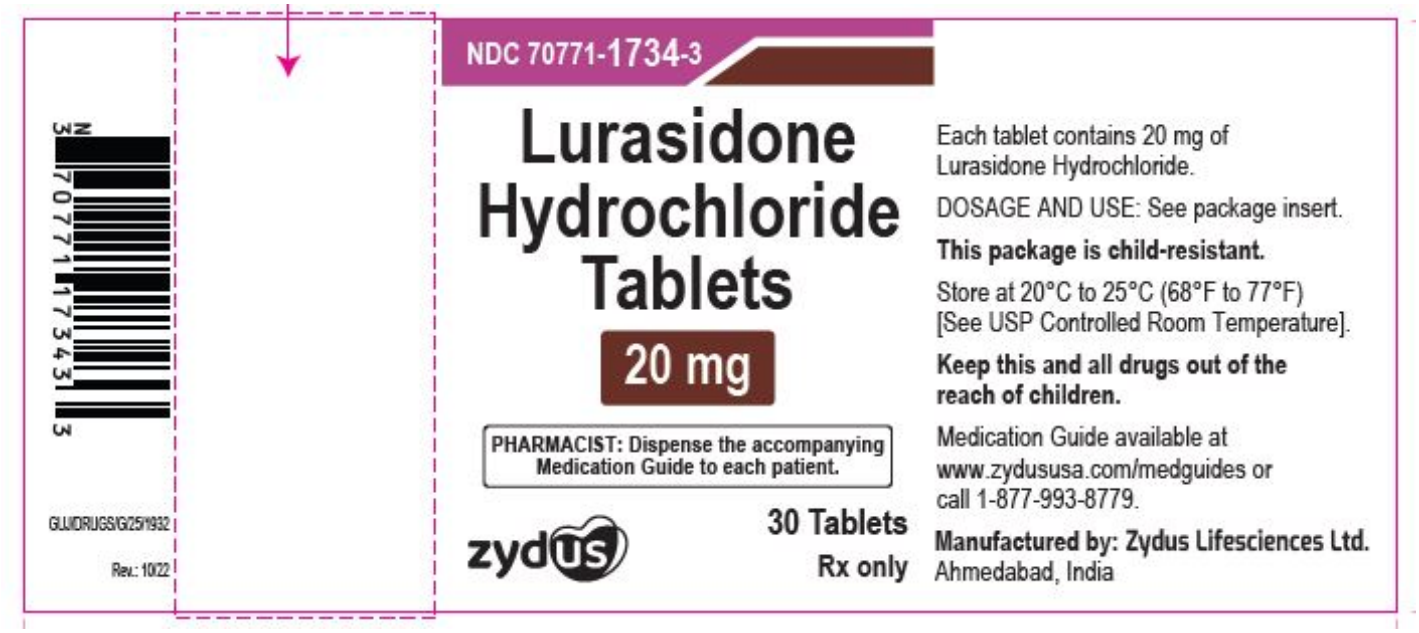
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1734-3

Lurasidone hydrochloride tablets, 20 mg

30 tablets

Rx only



NDC 70771-1735-9

Lurasidone hydrochloride tablets, 40 mg

90 tablets

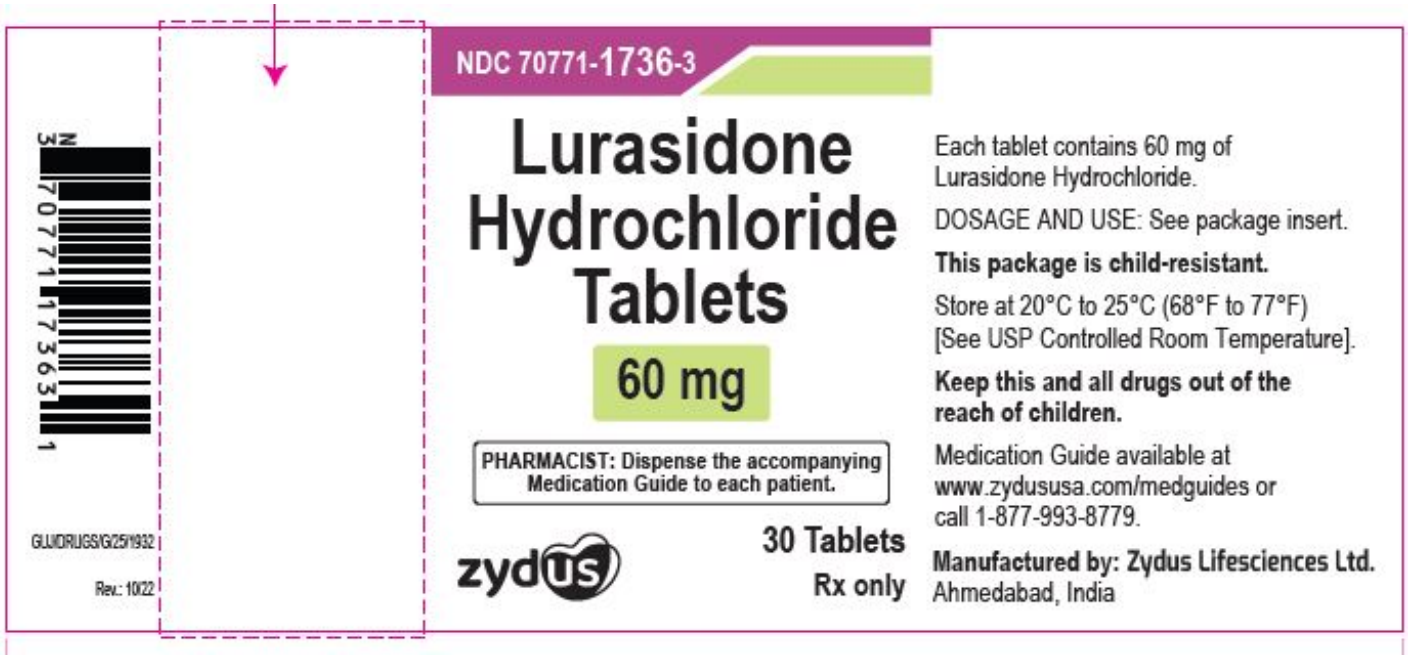
Rx only

NDC 70771-1736-3

Lurasidone hydrochloride tablets, 60 mg

30 tablets

Rx only

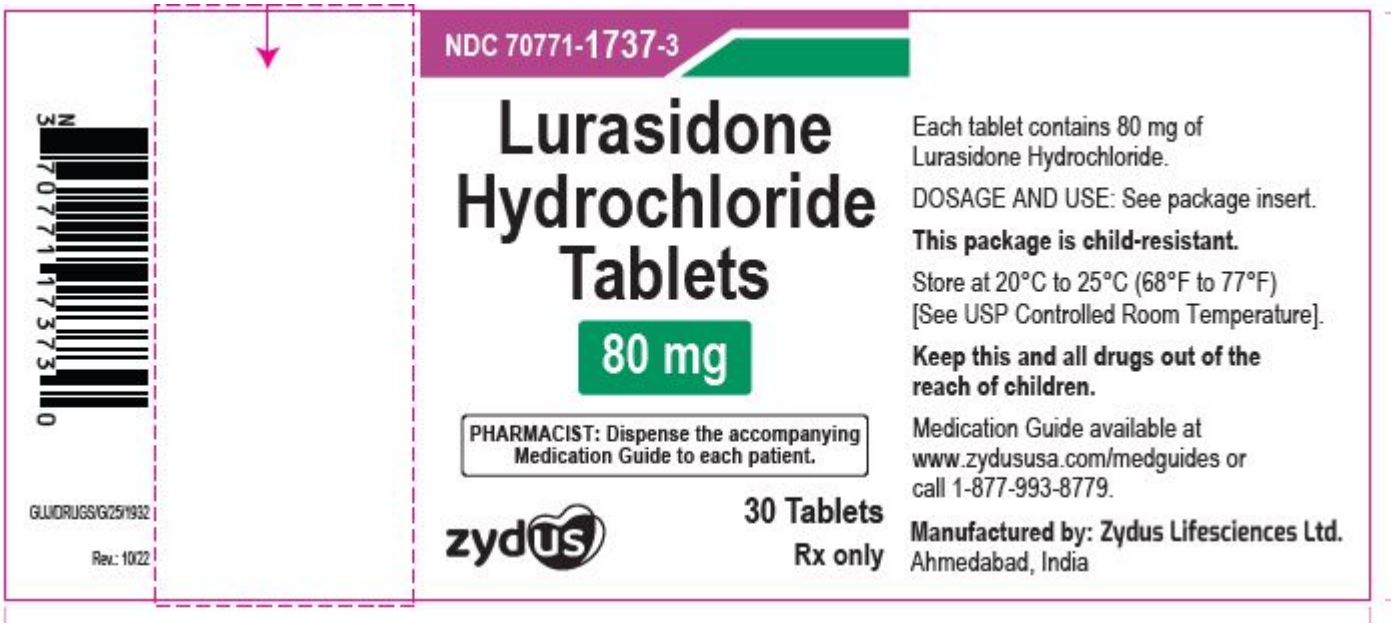


NDC 70771-1737-3

Lurasidone hydrochloride tablets, 80 mg

30 tablets

Rx only



NDC 70771-1738-3

Lurasidone hydrochloride tablets, 120 mg

30 tablets

Rx only

LURASIDONE HYDROCHLORIDE

lurasidone hydrochloride tablet, coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1734

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LURASIDONE HYDROCHLORIDE (UNII: O0P4I5851I) (LURASIDONE - UNII:22IC88528T)	LURASIDONE HYDROCHLORIDE	20 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (YELLOW TO LIGHT YELLOW)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	6mm
Flavor		**Imprint Code**	C31
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1734-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
2	NDC:70771-1734-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
3	NDC:70771-1734-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
4	NDC:70771-1734-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
5	NDC:70771-1734-4	10 in 1 CARTON	02/01/2023	
5	NDC:70771-1734-2	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	ANDA208052	02/01/2023	

LURASIDONE HYDROCHLORIDE

lurasidone hydrochloride tablet, coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1735
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LURASIDONE HYDROCHLORIDE (UNII: O0P4I5851I) (LURASIDONE - UNII:22IC88528T)	LURASIDONE HYDROCHLORIDE	40 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	8mm
Flavor		**Imprint Code**	C32
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1735-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	

2	NDC:70771-1735-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
3	NDC:70771-1735-4	10 in 1 CARTON	02/01/2023	
3	NDC:70771-1735-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:70771-1735-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
5	NDC:70771-1735-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208052	02/01/2023	

LURASIDONE HYDROCHLORIDE

lurasidone hydrochloride tablet, coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1736
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LURASIDONE HYDROCHLORIDE (UNII: O0P4I5851I) (LURASIDONE - UNII:22IC88528T)	LURASIDONE HYDROCHLORIDE	60 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF WHITE)	**Score**	no score
Shape	CAPSULE (MODIFIED CAPSULE)	**Size**	13mm
Flavor		**Imprint Code**	C33
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1736-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
2	NDC:70771-1736-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
3	NDC:70771-1736-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
4	NDC:70771-1736-4	10 in 1 CARTON	02/01/2023	
4	NDC:70771-1736-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:70771-1736-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208052	02/01/2023	

LURASIDONE HYDROCHLORIDE

lurasidone hydrochloride tablet, coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1737
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LURASIDONE HYDROCHLORIDE (UNII: O0P4I5851I) (LURASIDONE - UNII:22IC88528T)	LURASIDONE HYDROCHLORIDE	80 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (YELLOW TO LIGHT YELLOW)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	12mm
Flavor		**Imprint Code**	C34
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1737-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
2	NDC:70771-1737-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
3	NDC:70771-1737-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
4	NDC:70771-1737-4	10 in 1 CARTON	02/01/2023	
4	NDC:70771-1737-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:70771-1737-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208052	02/01/2023	

LURASIDONE HYDROCHLORIDE

lurasidone hydrochloride tablet, coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1738
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LURASIDONE HYDROCHLORIDE (UNII: O0P4I5851I) (LURASIDONE - UNII:22IC88528T)	LURASIDONE HYDROCHLORIDE	120 mg

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics

Color	WHITE (WHITE TO OFF WHITE)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	15mm
Flavor		**Imprint Code**	C35
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1738-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
2	NDC:70771-1738-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
3	NDC:70771-1738-4	10 in 1 CARTON	02/01/2023	
3	NDC:70771-1738-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:70771-1738-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
5	NDC:70771-1738-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208052	02/01/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1734, 70771-1735, 70771-1736, 70771-1737, 70771-1738) , MANUFACTURE(70771-1734, 70771-1735, 70771-1736, 70771-1737, 70771-1738)

Revised: 9/2023 Zydus Lifesciences Limited