

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

The image shows the principal display panel for Lurasidone Hydrochloride Tablets, 20 mg, 30 Tablets, Rx only. The panel is divided into several sections:

- Top Left:** A barcode with the NDC number 70771-1734-3 printed vertically to its left. Below the barcode is the text "GLUIDRUGS/G25/1932" and "Rev: 10/22".
- Top Center:** A dark blue banner with the NDC number "NDC 70771-1734-3" in white.
- Center:** The product name "Lurasidone Hydrochloride Tablets" in large, bold, black font. Below it, "20 mg" is displayed in white text on a dark blue rectangular background.
- Bottom Center:** A white box with a black border containing the text "PHARMACIST: Dispense the accompanying Medication Guide to each patient." Below this is the Zydus logo.
- Bottom Right:** The text "30 Tablets" and "Rx only" in bold black font.
- Right Side:** A column of text providing additional information: "Each tablet contains 20 mg of Lurasidone Hydrochloride.", "DOSAGE AND USE: See package insert.", "This package is child-resistant.", "Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].", "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.", and "Manufactured by: Zydus Lifesciences Ltd. Ahmedabad, India".

NDC 70771-1735-9

Lurasidone hydrochloride tablets, 40 mg

90 tablets

Rx only

NDC 70771-1735-9



Lurasidone Hydrochloride Tablets

40 mg

PHARMACIST: Dispense the accompanying Medication Guide to each patient.



90 Tablets
Rx only

Each tablet contains 40 mg of Lurasidone Hydrochloride.
DOSAGE AND USE: See package insert.
This package is child-resistant.
Store at 20°C to 25°C (68°F to 77°F)
[See USP Controlled Room Temperature].
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: Zydus Lifesciences Ltd.
Ahmedabad, India

GLUIDRUGS/G25/1932
Rev: 10/22

NDC 70771-1736-3

Lurasidone hydrochloride tablets, 60 mg

30 tablets

Rx only

NDC 70771-1736-3



Lurasidone Hydrochloride Tablets

60 mg

PHARMACIST: Dispense the accompanying Medication Guide to each patient.



30 Tablets
Rx only

Each tablet contains 60 mg of Lurasidone Hydrochloride.
DOSAGE AND USE: See package insert.
This package is child-resistant.
Store at 20°C to 25°C (68°F to 77°F)
[See USP Controlled Room Temperature].
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: Zydus Lifesciences Ltd.
Ahmedabad, India

GLUIDRUGS/G25/1932
Rev: 10/22

NDC 70771-1737-3

Lurasidone hydrochloride tablets, 80 mg

30 tablets

Rx only

NDC 70771-1737-3



Lurasidone Hydrochloride Tablets

80 mg

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

zydus

30 Tablets
Rx only

Each tablet contains 80 mg of Lurasidone Hydrochloride.
DOSAGE AND USE: See package insert.
This package is child-resistant.
Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].
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: Zydus Lifesciences Ltd.
Ahmedabad, India

GLJDRUGSIG/251932
Rev: 10/22

NDC 70771-1738-3

Lurasidone hydrochloride tablets, 120 mg

30 tablets

Rx only

NDC 70771-1738-3



Lurasidone Hydrochloride Tablets

120 mg

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

zydus

30 Tablets
Rx only

Each tablet contains 120 mg of Lurasidone Hydrochloride.
DOSAGE AND USE: See package insert.
This package is child-resistant.
Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].
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: Zydus Lifesciences Ltd.
Ahmedabad, India

GLJDRUGSIG/251932
Rev: 10/22

LURASIDONE HYDROCHLORIDE

lurasidone hydrochloride tablet, coated

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:70771-1734

Route of Administration	ORAL
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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: TUF2IWW3M2)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLOXAMER 407 (UNII: TUF2IWW3M2)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLOXAMER 407 (UNII: TUF2IWW3M2)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
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: 70097M6I3O)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLOXAMER 407 (UNII: TUF2IWW3M2)	
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: 11/2024

Zydus Lifesciences Limited