

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 number 707711173431 printed vertically to its left. Above the barcode is the number 3, and below it is the number 5.
- Top Center:** The NDC number 70771-1734-3 is printed in a dark blue box.
- Center:** The product name "Lurasidone Hydrochloride Tablets" is printed in large, bold, black letters. Below it, the strength "20 mg" is printed in white on a dark blue background.
- Bottom Center:** The Zydus logo is displayed.
- Bottom Right:** The text "30 Tablets" and "Rx only" is printed.
- Right Side:** Detailed product information is provided, including: "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".
- Bottom Left:** The text "GLUIDRUGS/G25/1932" and "Rev: 10/22" is printed.

NDC 70771-1735-9

Lurasidone hydrochloride tablets, 40 mg

90 tablets

Rx only

NDC 70771-1735-9



GLUIDRUGS/G25/1932
Rev: 10/22

Lurasidone Hydrochloride Tablets

40 mg

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

zydus

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

NDC 70771-1736-3

Lurasidone hydrochloride tablets, 60 mg

30 tablets

Rx only

NDC 70771-1736-3



GLUIDRUGS/G25/1932
Rev: 10/22

Lurasidone Hydrochloride Tablets

60 mg

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

zydus

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

NDC 70771-1737-3

Lurasidone hydrochloride tablets, 80 mg

30 tablets

Rx only

NDC 70771-1737-3



3
70771
17373
0

GLJDRUGSIG/251932
Rev: 10/22

Lurasidone Hydrochloride Tablets

80 mg

PHARMACIST: Dispense the accompanying Medication Guide to each patient.



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

NDC 70771-1738-3

Lurasidone hydrochloride tablets, 120 mg

30 tablets

Rx only

NDC 70771-1738-3



3
70771
17383
9

GLJDRUGSIG/251932
Rev: 10/22

Lurasidone Hydrochloride Tablets

120 mg

PHARMACIST: Dispense the accompanying Medication Guide to each patient.



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

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: 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: 70097M6I30) | |
| 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: 9/2023

Zydus Lifesciences Limited