

**TRAMADOL HYDROCHLORIDE- tramadol hydrochloride tablet, film coated**  
**Zydus Lifesciences Limited**

**TRAMADOL HYDROCHLORIDE TABLETS C-IV**

**SPL MEDGUIDE**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Tramadol Hydrochloride Tablets USP, 50 mg

NDC 65841-754-01 in bottle of 100 tablets

100 tablets

Rx only



**TRAMADOL HYDROCHLORIDE**

tramadol hydrochloride tablet, film coated

**Product Information**

|                                |                         |                           |               |
|--------------------------------|-------------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:65841-754 |
| <b>Route of Administration</b> | ORAL                    | <b>DEA Schedule</b>       | CIV           |

**Active Ingredient/Active Moiety**

| Ingredient Name                                       | Basis of Strength | Strength |
|---|-------------------|----------|
| TRAMADOL HYDROCHLORIDE (UNII: 9N7R477WCK) (TRAMADOL - | TRAMADOL          | 50 mg    |

UNII:39J1LGJ30J)

HYDROCHLORIDE

50 mg

**Inactive Ingredients**

| Ingredient Name   | Strength |
|---|----------|
| <b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)                     |          |
| <b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)                         |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)                    |          |
| <b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)      |          |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)                        |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                       |          |
| <b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2) |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                      |          |
| <b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)           |          |

**Product Characteristics**

|                 |                            |                     |          |
|-----------------|----------------------------|---------------------|----------|
| <b>Color</b>    | WHITE (WHITE TO OFF-WHITE) | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND (ROUND)              | <b>Size</b>         | 9mm      |
| <b>Flavor</b>   |                            | <b>Imprint Code</b> | 319      |
| <b>Contains</b> |                            |                     |          |

**Packaging**

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:65841-754-30 | 10 in 1 CARTON  | 01/31/2011           |                    |
| 1 |                  | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:65841-754-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product      | 01/31/2011           |                    |
| 3 | NDC:65841-754-05 | 500 in 1 BOTTLE; Type 0: Not a Combination Product      | 01/31/2011           |                    |
| 4 | NDC:65841-754-10 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product     | 01/31/2011           |                    |

**Marketing Information**

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA090404                               | 01/31/2011           |                    |

**Labeler** - Zydus Lifesciences Limited (918596198)**Registrant** - Zydus Lifesciences Limited (677605858)**Establishment**

| <b>Name</b>                | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b>                   |
|----------------------------|----------------|---------------|--|
| Zyduş Lifesciences Limited |                | 918596198     | ANALYSIS(65841-754) , MANUFACTURE(65841-754) |

## **Establishment**

| <b>Name</b>                | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b>                   |
|----------------------------|----------------|---------------|--|
| Zyduş Lifesciences Limited |                | 677605858     | ANALYSIS(65841-754) , MANUFACTURE(65841-754) |

Revised: 9/2023

Zyduş Lifesciences Limited