

**AZATHIOPRINE- azathioprine tablet**  
**Zydus Lifesciences Limited**

**Azathioprine Tablets, USP**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 65841-602-01 in bottle of 100 tablets

Azathioprine Tablets USP, 50 mg

100 tablets

Rx only



**AZATHIOPRINE**

azathioprine tablet

**Product Information**

|                                |                         |                           |               |
|--------------------------------|-------------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:65841-602 |
| <b>Route of Administration</b> | ORAL                    |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength | Strength |
|---|-------------------|----------|
| <b>AZATHIOPRINE</b> (UNII: MRK240IY2L) (AZATHIOPRINE - UNII:MRK240IY2L) | AZATHIOPRINE      | 50 mg    |

## Inactive Ingredients

| Ingredient Name                         | Strength |
|---|----------|
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) |          |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)  |          |
| MAGNESIUM STEARATE (UNII: 70097M6I30)   |          |
| POVIDONE (UNII: FZ989GH94E)             |          |
| STARCH, CORN (UNII: O8232NY3SJ)         |          |

## Product Characteristics

|          |                 |              |          |
|----------|-----------------|--------------|----------|
| Color    | YELLOW (YELLOW) | Score        | 2 pieces |
| Shape    | ROUND (ROUND)   | Size         | 8mm      |
| Flavor   |                 | Imprint Code | ZC;59    |
| Contains |                 |              |          |

## Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:65841-602-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 07/11/2007           |                    |
| 2 | NDC:65841-602-05 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 07/11/2007           |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA077621                               | 07/11/2007           |                    |

**Labeler** - Zydus Lifesciences Limited (918596198)

**Registrant** - Zydus Lifesciences Limited (918596198)

## Establishment

| Name                       | Address | ID/FEI    | Business Operations                          |
|----------------------------|---------|-----------|--|
| Zydus Lifesciences Limited |         | 918596198 | ANALYSIS(65841-602) , MANUFACTURE(65841-602) |

Revised: 11/2024

Zydus Lifesciences Limited