

ROFLUMILAST- roflumilast tablet
Zydus Lifesciences Limited

Roflumilast Tablets, for oral use

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1674-3

Roflumilast Tablets, 500 mcg

30 tablets

Rx only

3 N
6 8 3 8 2 1 9 6 9 0 6 1 4

**Roflumilast
Tablets**

500 mcg

**PHARMACIST: Dispense the Medication
Guide provided separately to each patient.**

zydus

30 Tablets
Rx only

Each tablet contains 500 mcg of roflumilast.
Dosage: The recommended dose for adults is one tablet (500 mcg) by mouth once a day. See package insert for full prescribing information.
This package is child-resistant.
Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°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.
Mfg. by: Zydus Lifesciences Ltd., Ahmedabad, India

GUJDRUGSIG/25/1932
XXXXXXXX
Rev.: 07/24

NDC 70771-1673-8

Roflumilast Tablets, 250 mcg

Blister pack of 28 tablets

Rx only

Form or supply : to be supplied in ounces
 Type and style : Reverse Tuck-In carton
 Note: Grain direction not included, as this carton is not used on auto-cartonato



JNE 2062 C PANTONE 321 C PANTONE 321 C PANTONE 108 C BLACK

Print Creasing Line (Do Not Print) No Varnished Area (Do Not Print)

ROFLUMILAST

roflumilast tablet

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70771-1674 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| ROFLUMILAST (UNII: 0P6C6ZOP5U) (ROFLUMILAST - UNII:0P6C6ZOP5U) | ROFLUMILAST | 500 ug |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14) | |

| | |
|---|--|
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| POLOXAMER 407 (UNII: TUF2IWW3M2) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |

Product Characteristics

| | | | |
|-----------------|-------------------|---------------------|----------|
| Color | WHITE (off-white) | Score | no score |
| Shape | ROUND | Size | 6mm |
| Flavor | | Imprint Code | T5 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70771-1674-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 10/03/2022 | |
| 2 | NDC:70771-1674-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 10/03/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA208303 | 10/03/2022 | |

ROFLUMILAST

roflumilast tablet

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70771-1673 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| ROFLUMILAST (UNII: 0P6C6ZOP5U) (ROFLUMILAST - UNII:0P6C6ZOP5U) | ROFLUMILAST | 250 ug |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |

| | |
|--|--|
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| POLOXAMER 407 (UNII: TUF2IVW3M2) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |

Product Characteristics

| | | | |
|-----------------|-------------------|---------------------|----------|
| Color | WHITE (off-white) | Score | no score |
| Shape | ROUND | Size | 6mm |
| Flavor | | Imprint Code | T6 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70771-1673-8 | 1 in 1 CARTON | 05/18/2023 | |
| 1 | | 28 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:70771-1673-3 | 2 in 1 CARTON | 05/18/2023 | |
| 2 | NDC:70771-1673-2 | 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 | ANDA208303 | 05/18/2023 | |

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|--|
| Zydus Lifesciences Limited | | 863362789 | ANALYSIS(70771-1673, 70771-1674) , MANUFACTURE(70771-1673, 70771-1674) |

Revised: 8/2024

Zydus Lifesciences Limited