

PIOGLITAZONE- pioglitazone tablet
Zydus Lifesciences Limited

PIOGLITAZONE TABLETS

SPL MEDGUIDE

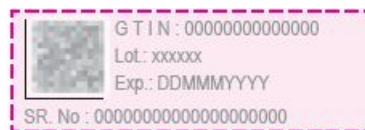
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1021-3 in bottle of 30 tablets

Pioglitazone Tablets USP, 15 mg

R_x only

30 tablets



Over Coding Template
No Varnished Area (Do Not Print)
(41 x 18 mm)

NDC 70771-1021-3

**Pioglitazone
Tablets, USP**

15 mg

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

30 Tablets
Rx only

Each tablet contains pioglitazone hydrochloride, USP equivalent to 15 mg of pioglitazone.
Usual Dosage: See package insert for complete prescribing information.
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
Protect from moisture and humidity.
Keep container tightly closed.
Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured by:
Cadila Healthcare Ltd., Ahmedabad, India

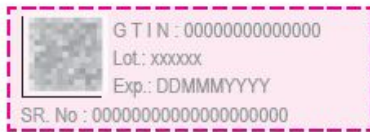
Rev-2018

NDC 70771-1022-3 in bottle of 30 tablets

Pioglitazone Tablets USP, 30 mg

R_x only

30 tablets



Over Coding Template

No Varnished Area (Do Not Print)
(41 x 18 mm)

NDC 70771-1022-3

**Pioglitazone
Tablets, USP**

30 mg

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

zydus
pharmaceuticals

30 Tablets
Rx only

Each tablet contains pioglitazone hydrochloride, USP equivalent to 30 mg of pioglitazone.
Usual Dosage: See package insert for complete prescribing information.
Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].
Protect from moisture and humidity.
Keep container tightly closed.
Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured by:
Cadila Healthcare Ltd., Ahmedabad, India

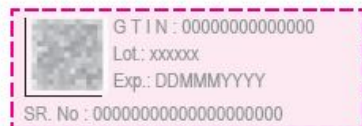
Rev: 10/18

NDC 70771-1023-3 in bottle of 30 tablets

Pioglitazone Tablets USP, 45 mg

R_x only

30 tablets



Over Coding Template

No Varnished Area (Do Not Print)
(41 x 18 mm)

NDC 70771-1023-3

**Pioglitazone
Tablets, USP**

45 mg

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

zydus
pharmaceuticals

30 Tablets
Rx only

Each tablet contains pioglitazone hydrochloride, USP equivalent to 45 mg of pioglitazone.
Usual Dosage: See package insert for complete prescribing information.
Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].
Protect from moisture and humidity.
Keep container tightly closed.
Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured by:
Cadila Healthcare Ltd., Ahmedabad, India

Rev: 10/18

PIOGLITAZONE

pioglitazone tablet

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70771-1021 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------|-------------------|----------|
| PIOGLITAZONE HYDROCHLORIDE (UNII: JQT35NPK6C) (PIOGLITAZONE - UNII:X4OV71U42S) | PIOGLITAZONE | 15 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------------------------|----------|
| CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH) | |

Product Characteristics

| | | | |
|-----------------|----------------------------------|---------------------|----------|
| Color | WHITE (off-white to cream white) | Score | no score |
| Shape | ROUND (ROUND) | Size | 6mm |
| Flavor | | Imprint Code | 306 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:70771-1021-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2016 | |
| 2 | NDC:70771-1021-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2016 | |
| 3 | NDC:70771-1021-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2016 | |
| 4 | NDC:70771-1021-5 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2016 | |
| 5 | NDC:70771-1021-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2016 | |
| 6 | NDC:70771-1021-4 | 10 in 1 CARTON | 11/16/2016 | |
| 6 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
| | | | |

| Category | Citation | Date | Date |
|----------|------------|------------|------|
| ANDA | ANDA202456 | 11/16/2016 | |

PIOGLITAZONE

pioglitazone tablet

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70771-1022 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------|-------------------|----------|
| PIOGLITAZONE HYDROCHLORIDE (UNII: JQT35NPK6C) (PIOGLITAZONE - UNII:X4OV71U42S) | PIOGLITAZONE | 30 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------------------------|----------|
| CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH) | |

Product Characteristics

| | | | |
|-----------------|----------------------------------|---------------------|----------|
| Color | WHITE (off-white to cream white) | Score | no score |
| Shape | ROUND (ROUND) | Size | 7mm |
| Flavor | | Imprint Code | 307 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:70771-1022-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2016 | |
| 2 | NDC:70771-1022-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2016 | |
| 3 | NDC:70771-1022-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2016 | |
| 4 | NDC:70771-1022-5 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2016 | |
| 5 | NDC:70771-1022-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2016 | |
| 6 | NDC:70771-1022-4 | 10 in 1 CARTON | 11/16/2016 | |
| 6 | | 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 | ANDA202456 | 11/16/2016 | |

PIOGLITAZONE

pioglitazone tablet

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70771-1023 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------|-------------------|----------|
| PIOGLITAZONE HYDROCHLORIDE (UNII: JQT35NPK6C) (PIOGLITAZONE - UNII:X4OV71U425) | PIOGLITAZONE | 45 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------------------------|----------|
| CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH) | |

Product Characteristics

| | | | |
|-----------------|----------------------------------|---------------------|----------|
| Color | WHITE (off-white to cream white) | Score | no score |
| Shape | ROUND (ROUND) | Size | 8mm |
| Flavor | | Imprint Code | 308 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:70771-1023-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2016 | |
| 2 | NDC:70771-1023-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2016 | |
| 3 | NDC:70771-1023-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2016 | |

| | | | | |
|---|------------------|---------------------------------------------------------|------------|--|
| 4 | NDC:70771-1023-5 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2016 | |
| 5 | NDC:70771-1023-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2016 | |
| 6 | NDC:70771-1023-4 | 10 in 1 CARTON | 11/16/2016 | |
| 6 | | 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 | ANDA202456 | 11/16/2016 | |

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|------------------------------------------------------------------------------------------------|
| Zydus Lifesciences Limited | | 918596198 | ANALYSIS(70771-1021, 70771-1022, 70771-1023) , MANUFACTURE(70771-1021, 70771-1022, 70771-1023) |

Revised: 9/2023

Zydus Lifesciences Limited