

**CANDESARTAN CILEXETIL - candesartan cilexetil tablet**  
**Zydus Lifesciences Limited**

**CANDESARTAN CILEXETIL TABLETS**

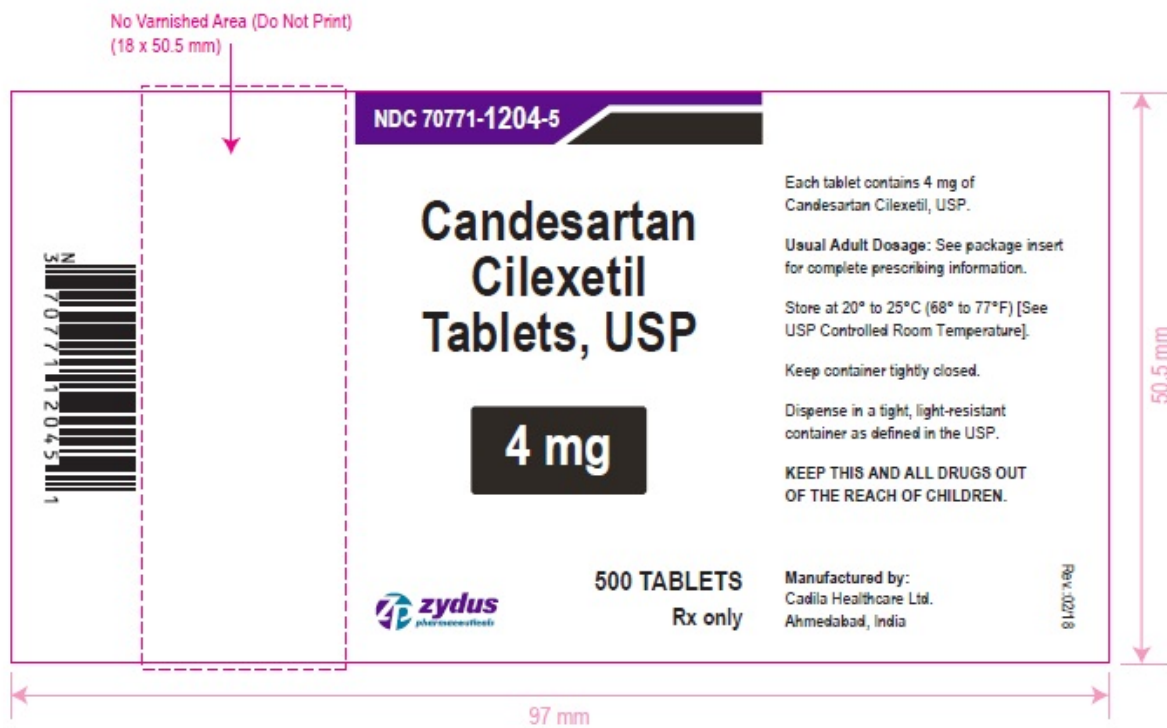
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1204-5

Candesartan Cilexetil Tablets USP, 4 mg

Rx Only

500 tablets

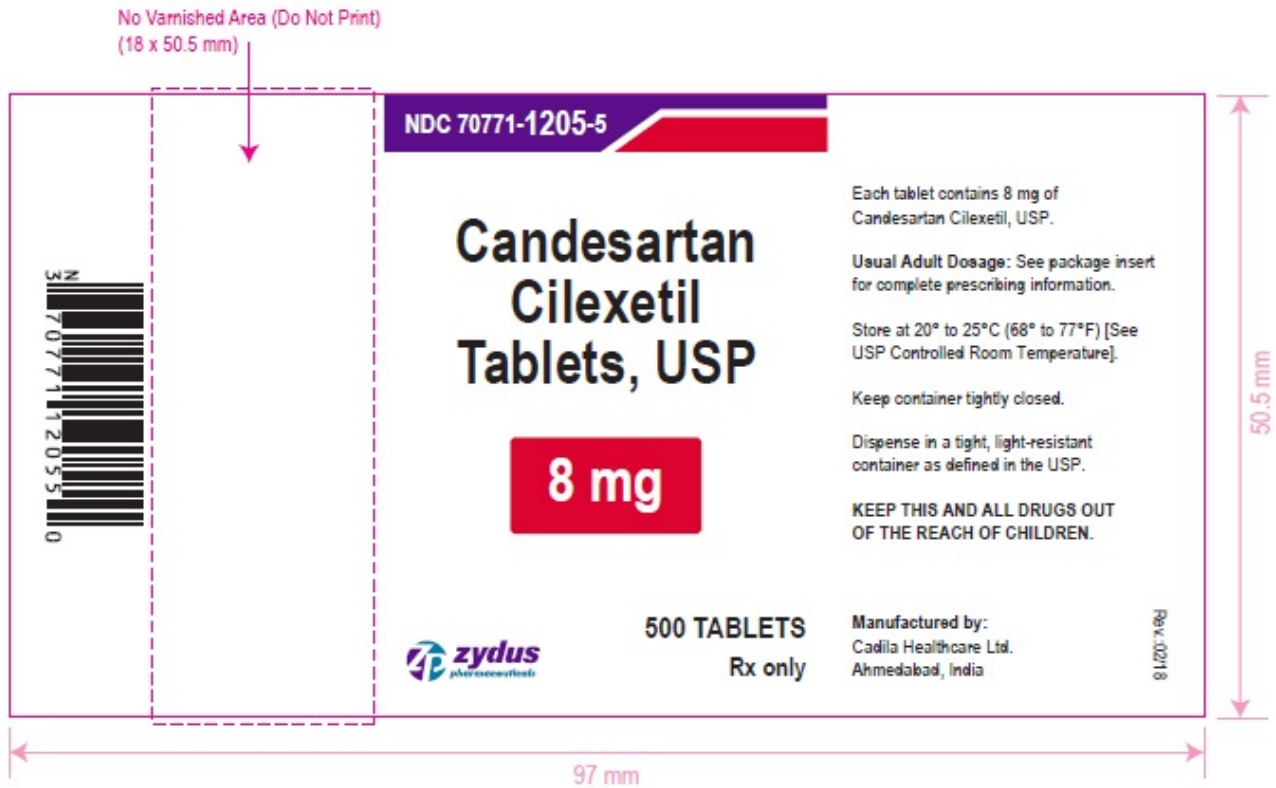


NDC 70771-1205-5

Candesartan Cilexetil Tablets USP, 8 mg

Rx Only

500 tablets

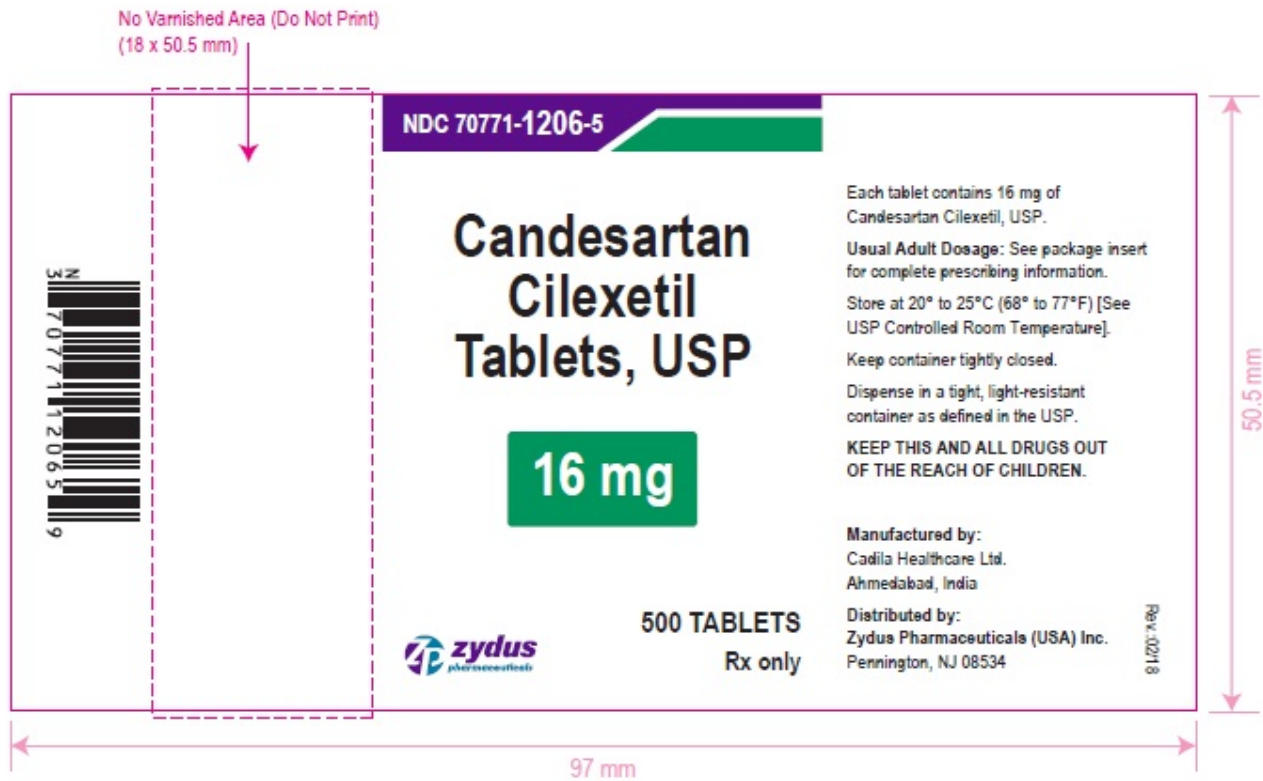


NDC 70771-1206-5

Candesartan Cilexetil Tablets USP, 16 mg

Rx Only

500 tablets

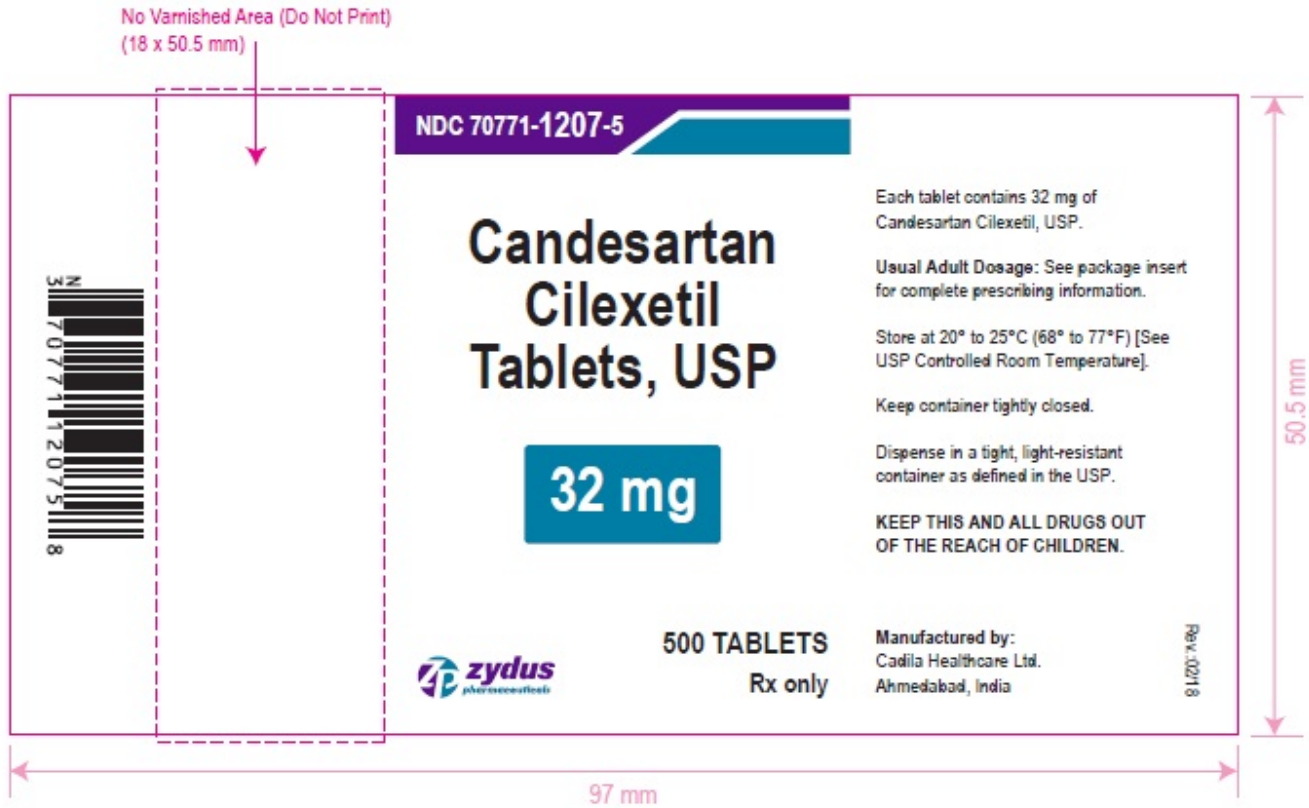


NDC 70771-1207-5

Candesartan Cilexetil Tablets USP, 32 mg

Rx Only

500 tablets



## CANDESARTAN CILEXETIL

candesartan cilexetil tablet

### Product Information

|                                |                         |                           |                |
|--------------------------------|-------------------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:70771-1204 |
| <b>Route of Administration</b> | ORAL                    |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength     | Strength |
|---|-----------------------|----------|
| <b>CANDESARTAN CILEXETIL</b> (UNII: R85M2X0D68) (CANDESARTAN - UNII:S8Q36MD2XX) | CANDESARTAN CILEXETIL | 4 mg     |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>CARBOXYMETHYLCELLULOSE CALCIUM</b> (UNII: UTY7PDF93L)        |          |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                      |          |
| <b>HYDROXYPROPYL CELLULOSE (110000 WAMW)</b> (UNII: 5Y0974F5PW) |          |
| <b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)                   |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)                    |          |
| <b>POLYETHYLENE GLYCOL 6000</b> (UNII: 30IQX730WE)              |          |
| <b>STARCH, CORN</b> (UNII: O8232NY3S)                           |          |

## Product Characteristics

|                 |                   |                     |          |
|-----------------|-------------------|---------------------|----------|
| <b>Color</b>    | PINK (LIGHT PINK) | <b>Score</b>        | 2 pieces |
| <b>Shape</b>    | ROUND (ROUND)     | <b>Size</b>         | 7mm      |
| <b>Flavor</b>   |                   | <b>Imprint Code</b> | ZE;58    |
| <b>Contains</b> |                   |                     |          |

## Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70771-1204-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product  | 02/22/2018           |                    |
| 2 | NDC:70771-1204-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product  | 02/22/2018           |                    |
| 3 | NDC:70771-1204-5 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 02/22/2018           |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA091390                               | 02/22/2018           |                    |

## CANDESARTAN CILEXETIL

candesartan cilexetil tablet

### Product Information

|                                |                         |                           |                |
|--------------------------------|-------------------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:70771-1205 |
| <b>Route of Administration</b> | ORAL                    |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength     | Strength |
|---|-----------------------|----------|
| <b>CANDESARTAN CILEXETIL</b> (UNII: R85M2X0D68) (CANDESARTAN - UNII:S8Q36MD2XX) | CANDESARTAN CILEXETIL | 8 mg     |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>CARBOXYMETHYLCELLULOSE CALCIUM</b> (UNII: UTY7PDF93L)        |          |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                      |          |
| <b>HYDROXYPROPYL CELLULOSE (110000 WAMW)</b> (UNII: 5Y0974F5PW) |          |
| <b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)                   |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)                    |          |
| <b>POLYETHYLENE GLYCOL 6000</b> (UNII: 30IQX730WE)              |          |
| <b>STARCH, CORN</b> (UNII: O8232NY3SJ)                          |          |

## Product Characteristics

|                 |               |                     |          |
|-----------------|---------------|---------------------|----------|
| <b>Color</b>    | PINK (PINK)   | <b>Score</b>        | 2 pieces |
| <b>Shape</b>    | ROUND (ROUND) | <b>Size</b>         | 7mm      |
| <b>Flavor</b>   |               | <b>Imprint Code</b> | ZE;59    |
| <b>Contains</b> |               |                     |          |

## Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70771-1205-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product  | 02/22/2018           |                    |
| 2 | NDC:70771-1205-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product  | 02/22/2018           |                    |
| 3 | NDC:70771-1205-5 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 02/22/2018           |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA091390                               | 02/22/2018           |                    |

## CANDESARTAN CILEXETIL

candesartan cilexetil tablet

### Product Information

|                                |                         |                           |                |
|--------------------------------|-------------------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:70771-1206 |
| <b>Route of Administration</b> | ORAL                    |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength     | Strength |
|--|-----------------------|----------|
| CANDESARTAN CILEXETIL (UNII: R85M2X0D68) (CANDESARTAN - UNII:S8Q36MD2XX) | CANDESARTAN CILEXETIL | 16 mg    |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L)        |          |
| HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW) |          |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)                   |          |
| MAGNESIUM STEARATE (UNII: 70097M6I30)                    |          |
| POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)              |          |
| STARCH, CORN (UNII: O8232NY3SJ)                          |          |

## Product Characteristics

|                 |               |                     |          |
|-----------------|---------------|---------------------|----------|
| <b>Color</b>    | WHITE (WHITE) | <b>Score</b>        | 2 pieces |
| <b>Shape</b>    | ROUND (ROUND) | <b>Size</b>         | 7mm      |
| <b>Flavor</b>   |               | <b>Imprint Code</b> | ZE;60    |
| <b>Contains</b> |               |                     |          |

## Packaging

| # | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70771-1206-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product   | 02/22/2018           |                    |
| 2 | NDC:70771-1206-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product   | 02/22/2018           |                    |
| 3 | NDC:70771-1206-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product  | 02/22/2018           |                    |
| 4 | NDC:70771-1206-5 | 500 in 1 BOTTLE; Type 0: Not a Combination Product  | 02/22/2018           |                    |
| 5 | NDC:70771-1206-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 02/22/2018           |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA091390                               | 02/22/2018           |                    |

## CANDESARTAN CILEXETIL

candesartan cilexetil tablet

### Product Information

|                                |                         |                           |                |
|--------------------------------|-------------------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:70771-1207 |
| <b>Route of Administration</b> | ORAL                    |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength     | Strength |
|---|-----------------------|----------|
| <b>CANDESARTAN CILEXETIL</b> (UNII: R85M2X0D68) (CANDESARTAN - UNII:S8Q36MD2XX) | CANDESARTAN CILEXETIL | 32 mg    |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>CARBOXYMETHYLCELLULOSE CALCIUM</b> (UNII: UTY7PDF93L)        |          |
| <b>HYDROXYPROPYL CELLULOSE (110000 WAMW)</b> (UNII: 5Y0974F5PW) |          |
| <b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)                   |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)                    |          |

**POLYETHYLENE GLYCOL 6000** (UNII: 30IQX730WE)

**STARCH, CORN** (UNII: O8232NY3SJ)

### Product Characteristics

|                 |                            |                     |          |
|-----------------|----------------------------|---------------------|----------|
| <b>Color</b>    | WHITE (WHITE TO OFF-WHITE) | <b>Score</b>        | 2 pieces |
| <b>Shape</b>    | ROUND (ROUND)              | <b>Size</b>         | 9mm      |
| <b>Flavor</b>   |                            | <b>Imprint Code</b> | ZE;61    |
| <b>Contains</b> |                            |                     |          |

### Packaging

| # | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70771-1207-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product   | 02/22/2018           |                    |
| 2 | NDC:70771-1207-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product   | 02/22/2018           |                    |
| 3 | NDC:70771-1207-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product  | 02/22/2018           |                    |
| 4 | NDC:70771-1207-5 | 500 in 1 BOTTLE; Type 0: Not a Combination Product  | 02/22/2018           |                    |
| 5 | NDC:70771-1207-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 02/22/2018           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA091390                               | 02/22/2018           |                    |

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

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

### Establishment

| Name                       | Address | ID/FEI    | Business Operations   |
|----------------------------|---------|-----------|---|
| Zydus Lifesciences Limited |         | 918596198 | ANALYSIS(70771-1204, 70771-1205, 70771-1206, 70771-1207) ,<br>MANUFACTURE(70771-1204, 70771-1205, 70771-1206, 70771-1207) |

Revised: 10/2022

Zydus Lifesciences Limited