

**AZITHROMYCIN- azithromycin powder, for suspension**  
**Zydus Lifesciences Limited**

**AZITHROMYCIN FOR ORAL SUSPENSION**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1422-1

Azithromycin for oral suspension, 300 mg

100 mg/5 mL

Rx only

**Azithromycin for Oral Suspension, USP**

**100 mg\* per 5 mL**

**300 mg (15 mL when mixed)**

**Cherry Flavored**

**zydus**

**Rx only**

**FOR ORAL USE ONLY**  
\*When constituted as directed, each teaspoonful (5 mL) contains azithromycin dihydrate, USP equivalent to 100 mg of azithromycin.  
Usual Dosage: See accompanying prescribing information. This package is child-resistant.  
Store dry powder 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].  
**PROTECT FROM FREEZING.**  
**MIXING DIRECTIONS:** Tap bottle to loosen powder. Add 9 mL of water to the bottle. After mixing, store suspension at 5°C to 30°C (41°F to 86°F). Oversized bottle provides extra space for shaking. After mixing, use within 10 days. Discard after full dosing is completed.  
**SHAKE WELL BEFORE USING.**  
Keep this and all drugs out of reach of children. Contains 300 mg azithromycin.  
Manufactured by: Zydus Lifesciences Ltd., Baddi, India

Rev.: 01/25

NDC 70771-1423-2

Azithromycin for oral suspension, 600 mg

200 mg/5 mL

Rx only

**Azithromycin for Oral Suspension, USP**

**200 mg\* per 5 mL**

**600 mg (15 mL when mixed)**

**Cherry Flavored**

**zydus** Rx only

FOR ORAL USE ONLY  
 \*When constituted as directed, each teaspoonful (5 mL) contains azithromycin dihydrate, USP equivalent to 200 mg of azithromycin.  
 Usual Dosage: See accompanying prescribing information. This package is child-resistant.  
 Store dry powder 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].  
 PROTECT FROM FREEZING.  
 MIXING DIRECTIONS: Tap bottle to loosen powder. Add 9 mL of water to the bottle. After mixing, store suspension at 5°C to 30°C (41°F to 86°F). Oversized bottle provides extra space for shaking. After mixing, use within 10 days. Discard after full dosing is completed.  
**SHAKE WELL BEFORE USING.**  
 Keep this and all drugs out of reach of children. Contains 600 mg azithromycin.  
 Manufactured by: Zydus Lifesciences Ltd., Baddi, India

Rev.: 01/25

NDC 70771-1424-2

Azithromycin for oral suspension, 900 mg

200 mg/5 mL

Rx only

**Azithromycin for Oral Suspension, USP**

**200 mg\* per 5 mL**

**900 mg (22.5 mL when mixed)**

**Cherry Flavored**

**zydus** Rx only

FOR ORAL USE ONLY  
 \*When constituted as directed, each teaspoonful (5 mL) contains azithromycin dihydrate, USP equivalent to 200 mg of azithromycin.  
 Usual Dosage: See accompanying prescribing information. This package is child-resistant.  
 Store dry powder 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].  
 PROTECT FROM FREEZING.  
 MIXING DIRECTIONS: Tap bottle to loosen powder. Add 12 mL of water to the bottle. After mixing, store suspension at 5°C to 30°C (41°F to 86°F). Oversized bottle provides extra space for shaking. After mixing, use within 10 days. Discard after full dosing is completed.  
**SHAKE WELL BEFORE USING.**  
 Keep this and all drugs out of reach of children. Contains 900 mg azithromycin.  
 Manufactured by: Zydus Lifesciences Ltd., Baddi, India

Rev.: 01/25

NDC 70771-1425-2

Azithromycin for oral suspension, 1200 mg

200 mg/5 mL

Rx only



Rev.: 01/25



## Azithromycin for Oral Suspension, USP

**200 mg\* per 5 mL**

1200 mg (30 mL when mixed)

Cherry Flavored



Rx only

**FOR ORAL USE ONLY**  
 \*When constituted as directed, each teaspoonful (5 mL) contains azithromycin dihydrate, USP equivalent to 200 mg of azithromycin.  
 Usual Dosage: See accompanying prescribing information.  
 This package is child-resistant.  
 Store dry powder 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].  
**PROTECT FROM FREEZING.**  
**MIXING DIRECTIONS:** Tap bottle to loosen powder. Add 15 mL of water to the bottle. After mixing, store suspension at 5°C to 30°C (41°F to 86°F). Oversized bottle provides extra space for shaking. After mixing, use within 10 days. Discard after full dosing is completed.  
**SHAKE WELL BEFORE USING.**  
 Keep this and all drugs out of reach of children. Contains 1200 mg azithromycin.  
 Manufactured by: Zydus Lifesciences Ltd., Baddi, India

## AZITHROMYCIN

azithromycin powder, for suspension

### Product Information

|                                |                         |                           |                |
|--------------------------------|-------------------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:70771-1422 |
| <b>Route of Administration</b> | ORAL                    |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength      | Strength       |
|---|------------------------|----------------|
| <b>AZITHROMYCIN DIHYDRATE</b> (UNII: 5FD1131I7S) (AZITHROMYCIN ANHYDROUS - UNII:J2KLZ20U1M) | AZITHROMYCIN ANHYDROUS | 100 mg in 5 mL |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)                   |          |
| <b>HYDROXYPROPYL CELLULOSE (90000 WAMW)</b> (UNII: UKE75GEA7F)  |          |
| <b>SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS</b> (UNII: SX01TZO3QZ) |          |
| <b>SUCROSE</b> (UNII: C151H8M554)                               |          |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)                           |          |

### Product Characteristics

| Color                                  | Score        |
|--|--------------|
| Shape                                  | Size         |
| Flavor                                 | Imprint Code |
| WHITE (WHITE TO LIGHT PINK)            |              |
| CHERRY (CHERRY) , BANANA (RIPE BANANA) |              |
| <b>Contains</b>                        |              |

## Packaging

| # | Item Code        | Package Description                                  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70771-1422-1 | 1 in 1 CARTON  | 08/06/2018           |                    |
| 1 |                  | 15 mL in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA211147                               | 08/06/2018           |                    |

## AZITHROMYCIN

azithromycin powder, for suspension

### Product Information

|                         |                         |                    |                |
|-------------------------|-------------------------|--------------------|----------------|
| Product Type            | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70771-1423 |
| Route of Administration | ORAL                    |                    |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength      | Strength       |
|---|------------------------|----------------|
| <b>AZITHROMYCIN DIHYDRATE</b> (UNII: 5FD1131I7S) (AZITHROMYCIN ANHYDROUS - UNII:J2KLZ20U1M) | AZITHROMYCIN ANHYDROUS | 200 mg in 5 mL |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)                   |          |
| <b>HYDROXYPROPYL CELLULOSE (90000 WAMW)</b> (UNII: UKE75GEA7F)  |          |
| <b>SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS</b> (UNII: SX01TZO3QZ) |          |
| <b>SUCROSE</b> (UNII: C151H8M554)                               |          |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)                           |          |

### Product Characteristics

|          |  |              |  |
|----------|--|--------------|--|
| Color    | WHITE (WHITE TO LIGHT PINK)            | Score        |  |
| Shape    |  | Size         |  |
| Flavor   | CHERRY (CHERRY) , BANANA (RIPE BANANA) | Imprint Code |  |
| Contains |  |              |  |

## Packaging

| # | Item Code | Package Description | Marketing Start | Marketing End |
|---|-----------|---------------------|-----------------|---------------|
|---|-----------|---------------------|-----------------|---------------|

| # | Item Code        | Package Description                                  | Date       | Date |
|---|------------------|--|------------|------|
| 1 | NDC:70771-1423-2 | 1 in 1 CARTON  | 08/06/2018 |      |
| 1 |                  | 15 mL in 1 BOTTLE; Type 0: Not a Combination Product |            |      |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA211147                               | 08/06/2018           |                    |

## AZITHROMYCIN

azithromycin powder, for suspension

### Product Information

|                         |                         |                    |                |
|-------------------------|-------------------------|--------------------|----------------|
| Product Type            | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70771-1424 |
| Route of Administration | ORAL                    |                    |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength      | Strength       |
|---|------------------------|----------------|
| <b>AZITHROMYCIN DIHYDRATE</b> (UNII: 5FD1131I7S) (AZITHROMYCIN ANHYDROUS - UNII:J2KLZ20U1M) | AZITHROMYCIN ANHYDROUS | 200 mg in 5 mL |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)                   |          |
| <b>HYDROXYPROPYL CELLULOSE (90000 WAMW)</b> (UNII: UKE75GEA7F)  |          |
| <b>SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS</b> (UNII: SX01TZO3QZ) |          |
| <b>SUCROSE</b> (UNII: C151H8M554)                               |          |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)                           |          |

### Product Characteristics

|          |  |              |  |
|----------|--|--------------|--|
| Color    | WHITE (WHITE TO LIGHT PINK)            | Score        |  |
| Shape    |  | Size         |  |
| Flavor   | CHERRY (CHERRY) , BANANA (RIPE BANANA) | Imprint Code |  |
| Contains |  |              |  |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:70771-1424-2 | 1 in 1 CARTON       | 08/06/2018           |                    |

|   |  |  |  |
|---|--|--|--|
| 1 | 22.5 mL in 1 BOTTLE; Type 0: Not a Combination Product |  |  |
|---|--|--|--|

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA211147                               | 08/06/2018           |                    |

## AZITHROMYCIN

azithromycin powder, for suspension

### Product Information

|                         |                         |                    |                |
|-------------------------|-------------------------|--------------------|----------------|
| Product Type            | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70771-1425 |
| Route of Administration | ORAL                    |                    |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength      | Strength       |
|---|------------------------|----------------|
| <b>AZITHROMYCIN DIHYDRATE</b> (UNII: 5FD1131I7S) (AZITHROMYCIN ANHYDROUS - UNII:J2KLZ20U1M) | AZITHROMYCIN ANHYDROUS | 200 mg in 5 mL |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)                   |          |
| <b>HYDROXYPROPYL CELLULOSE (90000 WAMW)</b> (UNII: UKE75GEA7F)  |          |
| <b>SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS</b> (UNII: SX01TZO3QZ) |          |
| <b>SUCROSE</b> (UNII: C151H8M554)                               |          |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)                           |          |

### Product Characteristics

|          |  |              |  |
|----------|--|--------------|--|
| Color    | WHITE (WHITE TO LIGHT PINK)            | Score        |  |
| Shape    |  | Size         |  |
| Flavor   | CHERRY (CHERRY) , BANANA (RIPE BANANA) | Imprint Code |  |
| Contains |  |              |  |

### Packaging

| # | Item Code        | Package Description                                  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70771-1425-2 | 1 in 1 CARTON  | 08/06/2018           |                    |
| 1 |                  | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA211147                               | 08/06/2018           |                    |

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

**Registrant** - Zydus Lifesciences Limited (677605858)

## Establishment

| Name                       | Address | ID/FEI    | Business Operations   |
|----------------------------|---------|-----------|---|
| Zydus Lifesciences Limited |         | 677605858 | ANALYSIS(70771-1422, 70771-1423, 70771-1424, 70771-1425) ,<br>MANUFACTURE(70771-1422, 70771-1423, 70771-1424, 70771-1425) |

Revised: 1/2025

Zydus Lifesciences Limited