

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

NDC 70771-1422-1

Azithromycin for Oral Suspension, USP

100 mg* per 5 mL

300 mg (15 mL when mixed)

Cherry Flavored

zydus
pharmaceuticals

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° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° 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:
Cadila Healthcare Ltd., Baddi, India

Rev: 08/18

NDC 70771-1423-2

Azithromycin for oral suspension, 600 mg

200 mg/5 mL

Rx only


NDC 70771-1423-2

Azithromycin for Oral Suspension, USP

200 mg* per 5 mL

600 mg (15 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° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° 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: Cadila Healthcare Ltd., Baddi, India

Rev: 0818

NDC 70771-1424-2
 Azithromycin for oral suspension, 900 mg
 200 mg/5 mL
 Rx only


NDC 70771-1424-2

Azithromycin for Oral Suspension, USP

200 mg* per 5 mL

900 mg (22.5 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° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° 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: Cadila Healthcare Ltd., Baddi, India

Rev: 0818

NDC 70771-1425-2
 Azithromycin for oral suspension, 1200 mg
 200 mg/5 mL
 Rx only




NDC 70771-1425-2

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° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° 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:
Cadila Healthcare Ltd., Baddi, India

Rev: 08/18

AZITHROMYCIN

azithromycin powder, for suspension

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1422
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AZITHROMYCIN DIHYDRATE (UNII: 5FD1131I7S) (AZITHROMYCIN ANHYDROUS - UNII:j2KLZ20U1M)	AZITHROMYCIN ANHYDROUS	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS (UNII: SX01TZO3QZ)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (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:70771-1422-1	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
AZITHROMYCIN DIHYDRATE (UNII: 5FD113117S) (AZITHROMYCIN ANHYDROUS - UNII:J2KLZ20U1M)	AZITHROMYCIN ANHYDROUS	200 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS (UNII: SX01TZO3QZ)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (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:70771-1423-2	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
AZITHROMYCIN DIHYDRATE (UNII: 5FD1131I7S) (AZITHROMYCIN ANHYDROUS - UNII:J2KLZ20U1M)	AZITHROMYCIN ANHYDROUS	200 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS (UNII: SX01TZO3QZ)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

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

Packaging

Marketing Start	Marketing End
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#	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
AZITHROMYCIN DIHYDRATE (UNII: 5FD1131I7S) (AZITHROMYCIN ANHYDROUS - UNII:J2KLZ20U1M)	AZITHROMYCIN ANHYDROUS	200 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS (UNII: SX01TZ03QZ)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (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
	NDC:70771			

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) , MANUFACTURE(70771-1422, 70771-1423, 70771-1424, 70771-1425)

Revised: 11/2022

Zydus Lifesciences Limited