

ERYTHROMYCIN- erythromycin tablet, film coated
Zydus Lifesciences Limited

Erythromycin Tablets, USP

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL

NDC 70771-1732-3 in bottle of 30 tablets

Erythromycin Tablets USP, 250 mg

Rx only

30 tablets



NDC 70771-1733-3 in bottle of 30 tablets

Erythromycin Tablets USP, 500 mg

Rx only

30 tablets



ERYTHROMYCIN

erythromycin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1732
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ERYTHROMYCIN (UNII: 63937KV33D) (ERYTHROMYCIN - UNII:63937KV33D)	ERYTHROMYCIN	250 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (120 .MU.M) (UNII: 68401960MK)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST) (UNII: G4U024CQK6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POVIDONE K30 (UNII: U725QWY32X)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
SORBIC ACID (UNII: X045WJ989B)				
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)				
Product Characteristics				
Color	PINK (peach to pink)		Score	no score
Shape	OVAL		Size	15mm
Flavor			Imprint Code	1755
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1732-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2023	
2	NDC:70771-1732-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2023	
3	NDC:70771-1732-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2023	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA215440	08/31/2023	

ERYTHROMYCIN			
erythromycin tablet, film coated			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1733
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ERYTHROMYCIN (UNII: 63937KV33D) (ERYTHROMYCIN - UNII:63937KV33D)		ERYTHROMYCIN	500 mg
Inactive Ingredients			
Ingredient Name			Strength

ALUMINUM OXIDE (UNII: LMI26O6933)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (120 .MU.M) (UNII: 68401960MK)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST) (UNII: G4U024CQK6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POVIDONE K30 (UNII: U725QWY32X)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBIC ACID (UNII: X045WJ989B)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Product Characteristics

Color	PINK (light pink to pink)	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	1756
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1733-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2023	
2	NDC:70771-1733-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2023	
3	NDC:70771-1733-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215440	08/31/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1732, 70771-1733) , MANUFACTURE(70771-1732, 70771-1733)

Revised: 10/2023

Zydus Lifesciences Limited