

ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium granule, delayed release

Zydus Lifesciences Limited

ESOMEPRAZOLE MAGNESIUM for delayed-release oral suspension

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Esomeprazole Magnesium For Delayed-Release Oral Suspension

NDC 70771-1391-1

20 mg packet

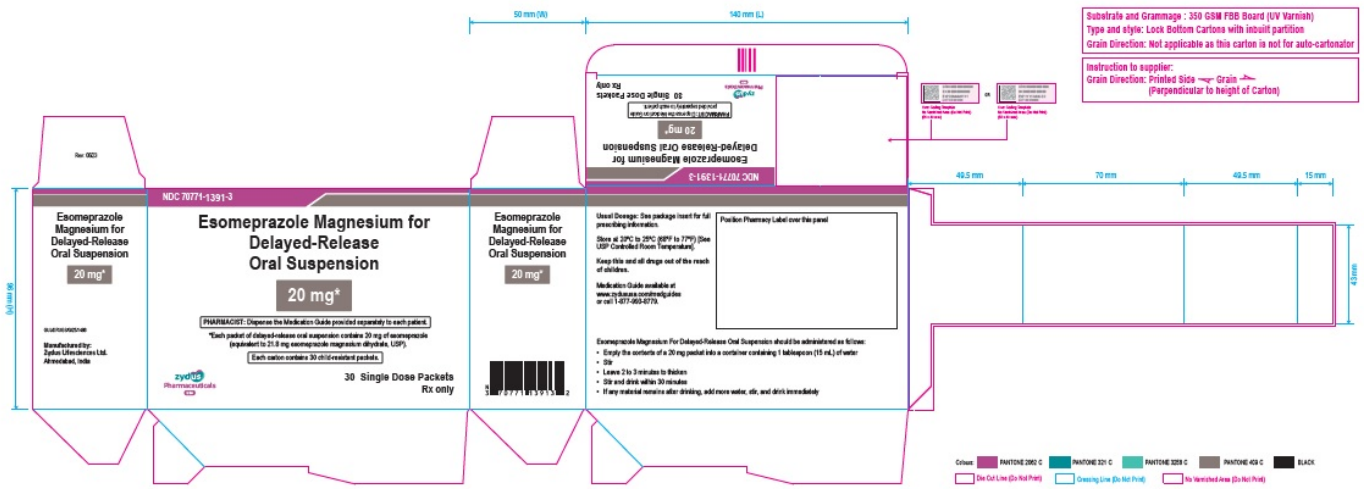
Rx Only



Esomeprazole Magnesium For Delayed-Release Oral Suspension

NDC 70771-1391-3 unit dose packages of 30: 20 mg packets

Rx Only



Esomeprazole Magnesium For Delayed-Release Oral Suspension

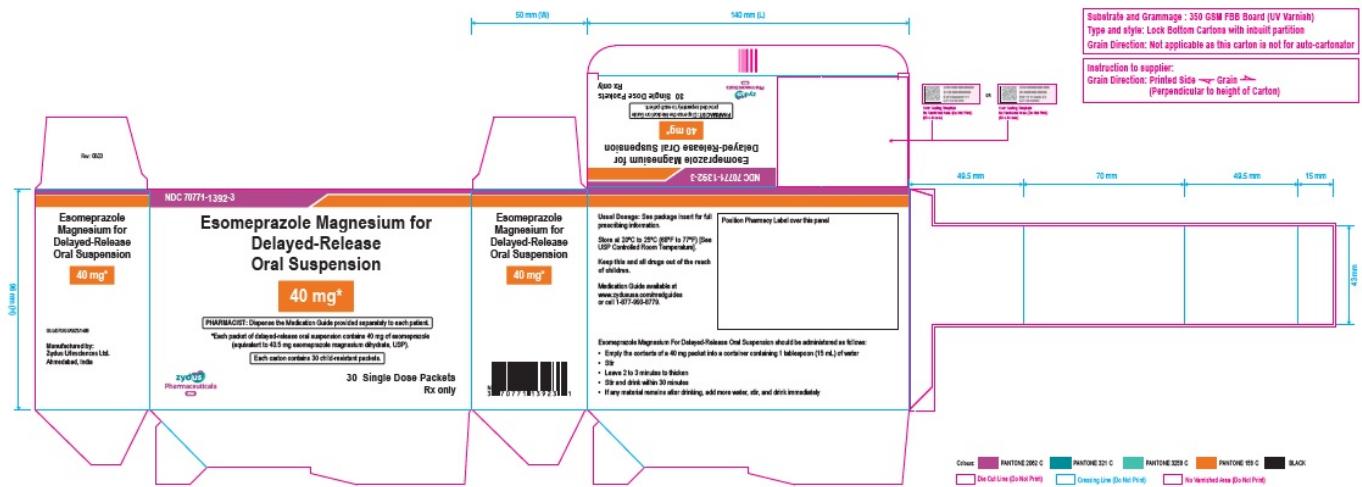
NDC 70771-1392-1

40 mg packet

Rx Only



Esomeprazole Magnesium For Delayed-Release Oral Suspension
 NDC 70771-1392-3 unit dose packages of 30: 40 mg packets
 Rx Only



ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium granule, delayed release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1391
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ESOMEPRAZOLE MAGNESIUM DIHYDRATE (UNII: 36H71644EQ) (ESOMEPRAZOLE - UNII:N3PA6559FT)	ESOMEPRAZOLE	20 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CROSPVIDONE (UNII: 2S7830E561)	
DEXTRROSE (UNII: IY9XDZ35W2)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE (UNII: FZ989GH94E)	
STRAWBERRY (UNII: 4J2TY8Y81V)	

SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	BROWN (WHITE TO PALE BROWN) , RED (PALE RED TO RED)	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1391-3	30 in 1 CARTON; Type 0: Not a Combination Product	06/30/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206055	06/30/2023	

ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium granule, delayed release

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Inactive Ingredients

Ingredient Name	Strength
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CROSPROVIDONE (UNII: 2S7830E561)	
DEXTROSE (UNII: IY9XDZ35W2)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

HYDROXYPROPYL CELLULOSE (TYPE E) (UNII: 66O7AQV0RT)
MAGNESIUM STEARATE (UNII: 70097M6I30)
MANNITOL (UNII: 3OWL53L36A)
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
POVIDONE (UNII: FZ989GH94E)
STRAWBERRY (UNII: 4J2TY8Y81V)
SUCROSE (UNII: C151H8M554)
TALC (UNII: 7SEV7J4R1U)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)
XANTHAN GUM (UNII: TTV12P4NEE)

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Flavor	STRAWBERRY	Imprint Code	
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ANDA	ANDA206055	06/30/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment			
Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1391, 70771-1392) , MANUFACTURE(70771-1391, 70771-1392)