

LOPINAVIR AND RITONAVIR- lopinavir and ritonavir granule

Mylan Laboratories Limited

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

The diagram illustrates the principal display panel for Lopinavir and Ritonavir Oral Granules. It includes the following elements:

- Top Panel:** Contains the Mylan logo, product name "Lopinavir and Ritonavir Oral Granules", and strength "40 mg/10 mg".
- Front Panel:** Features the product name and strength, a warning: "ALERT: Find out about medicines that should NOT be taken with Lopinavir and Ritonavir Oral Granules", and a pharmacist instruction: "Attention Pharmacist: Do not cover ALERT box or expiration date with pharmacy label. Store and dispense in original container." It also includes a barcode area and the text "AREA FOR DISPENSING PHARMACY LABEL".
- Back Panel:** Contains detailed information including "Each sachet contains: Lopinavir, USP 40 mg; Ritonavir, USP 10 mg", "Inactive Ingredients", "Directions for Use", and "Usual Dosage".
- Bottom Panel:** Displays "120 Sachets", "Rx only", and the Mylan logo.

LOPINAVIR AND RITONAVIR

lopinavir and ritonavir granule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:650 15-299
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LOPINAVIR (UNII: 2494G1JF75) (LOPINAVIR - UNII:2494G1JF75)	LOPINAVIR	40 mg in 50 mg
RITONAVIR (UNII: O3J8G9O825) (RITONAVIR - UNII:O3J8G9O825)	RITONAVIR	10 mg in 50 mg

Inactive Ingredients

Ingredient Name	Strength
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ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
MANNITOL (UNII: 3OWL53L36A)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
VANILLA (UNII: Q74T35078H)	

Product Characteristics

Color	WHITE (white to creamish)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65015-299-50	120 in 1 CARTON	02/06/2019	
1	NDC:65015-299-49	50 mg in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		02/06/2019	

Labeler - Mylan Laboratories Limited (650547156)