

DOLUTEGRAVIR- dolutegravir tablet, for suspension
Mylan Laboratories Limited

PRINCIPAL DISPLAY PANEL - 10 mg

<p>Each film-coated tablet contains dolutegravir 10 mg, equivalent to 10.52 mg of dolutegravir sodium.</p> <p>Usual Dosage: See accompanying prescribing information.</p> <p>Keep this and all medication out of the reach of children.</p> <p>Store below 30°C (86°F).</p> <p>Manufactured by: Mylan Laboratories Limited Hyderabad – 500 096, India</p>	<p>NDC 65015-353-14</p> <p>Dolutegravir Tablets for Oral Suspension</p> <p>10 mg</p> <p>Dolutegravir Tablets for Oral Suspension and Dolutegravir Tablets are not interchangeable.</p> <p>Do not chew or crush tablet for oral suspension, but can be split on the breakline.</p> <p>30 Tablets Rx only</p> <p>Mylan.com </p>	 <p>N 3 65015-353-14 6</p> <p>Store and dispense in the original bottle, protect from moisture and keep the bottle tightly closed. Do not remove desiccant.</p> <p>Code No.: MP/DRUGS/25/1/2014</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">750XXXXX</p> <p style="text-align: center;">(47 x 18 mm) Varnish Free area for Variable Data Coding</p>
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DOLUTEGRAVIR

dolutegravir tablet, for suspension

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65015-353
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOLUTEGRAVIR SODIUM (UNII: 1Q1V9V5WYQ) (DOLUTEGRAVIR - UNII:DKO1W9H7M1)	DOLUTEGRAVIR	10 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM SULFATE DIHYDRATE (UNII: 4846Q921YM)	
CROSPVIDONE (UNII: 2S7830E561)	
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	

FERROSFERRIC OXIDE (UNII: XM0M87F357)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	PINK	Score	2 pieces
Shape	OVAL	Size	12mm
Flavor	STRAWBERRY (strawberry cream)	Imprint Code	D;T;M
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65015-353-14	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2020	
2	NDC:65015-353-17	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2020	
3	NDC:65015-353-18	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		11/19/2020	

Labeler - Mylan Laboratories Limited (650547156)

Revised: 3/2021

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