

**TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN- tramadol hydrochloride and acetaminophen tablet, film coated**  
**Cadila Healthcare Limited**

**TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN TABLETS, C-IV**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Tramadol Hydrochloride and Acetaminophen Tablets USP, 37.5 mg/325 mg

NDC 65841-758-01

100 Tablets

Rx only



**TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN**

tramadol hydrochloride and acetaminophen tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-758
<b>Route of Administration</b>	ORAL	<b>DEA Schedule</b>	CIV

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
TRAMADOL HYDROCHLORIDE (UNII: 9N7R477WCK) (TRAMADOL - UNII:39J1LGJ30J)	TRAMADOL HYDROCHLORIDE	37.5 mg

**Inactive Ingredients**

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

Color	WHITE (WHITE)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	15mm
Flavor		Imprint Code	334
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-758-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/15/2012	
2	NDC:65841-758-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/15/2012	
3	NDC:65841-758-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/15/2012	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090460	10/15/2012	

**Labeler** - Cadila Healthcare Limited (918596198)

**Registrant** - Cadila Healthcare Limited (918596198)

### Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	ANALYSIS(65841-758) , MANUFACTURE(65841-758)

Revised: 9/2020

Cadila Healthcare Limited