

TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN- tramadol hydrochloride and acetaminophen tablet, film coated
Zydus Lifesciences Limited

TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN TABLETS, C-IV

SPL MEDGUIDE

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

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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: 70097M6I3O)				
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 - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

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

