

RAMELTEON- ramelteon tablet
Zydus Lifesciences Limited

RAMELTEON TABLETS

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1495-3

Ramelteon Tablets, 8 mg

30 Tablets

Rx only



RAMELTEON

ramelteon tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1495
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RAMELTEON (UNII: 901AS54I69) (RAMELTEON - UNII:901AS54I69)	RAMELTEON	8 mg

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
POLYETHYLENE GLYCOL 6000 (UNII: 3OIQX730WE)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	YELLOW (light yellow to beige coloured)	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	1344
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1495-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2019	
2	NDC:70771-1495-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2019	
3	NDC:70771-1495-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211567	07/23/2019	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment			
Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1495) , MANUFACTURE(70771-1495)

