MODAFINIL- modafinil tablet
Zydus Lifesciences Limited

MODAFINIL TABLETS CIV

SPL MEDGUIDE

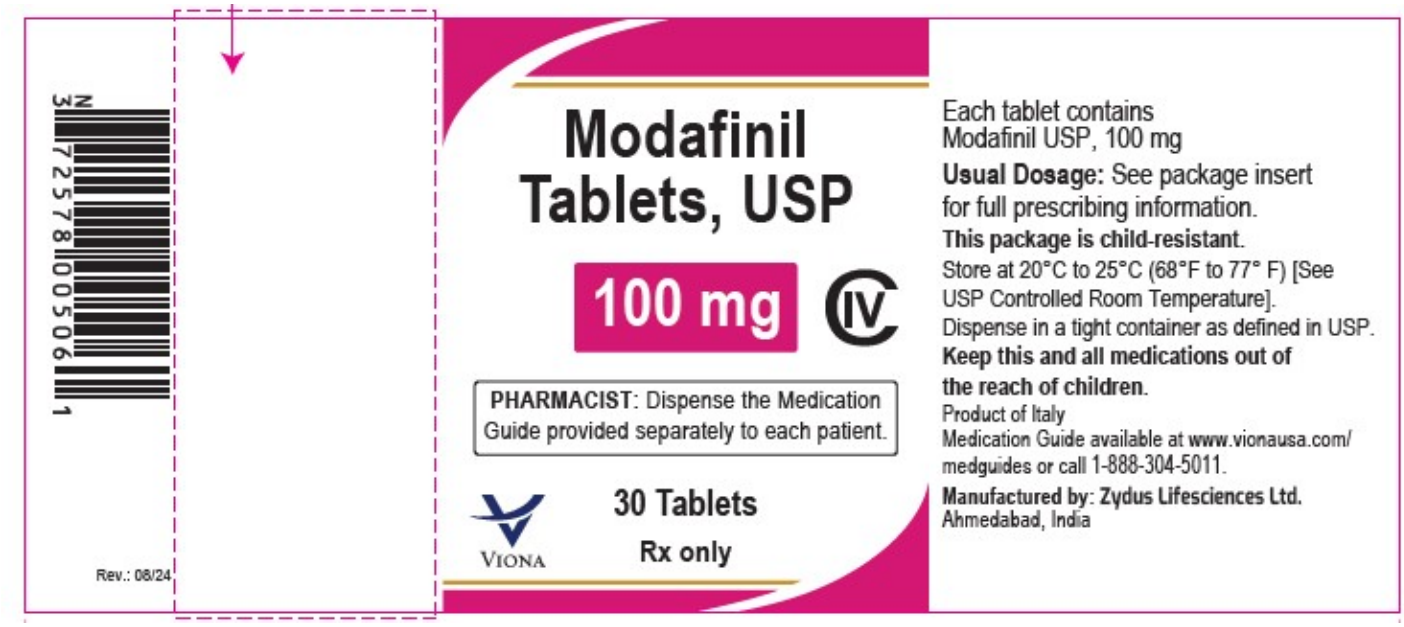
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1051-3

Modafinil Tablets USP, 100 mg

30 Tablets

Rx only

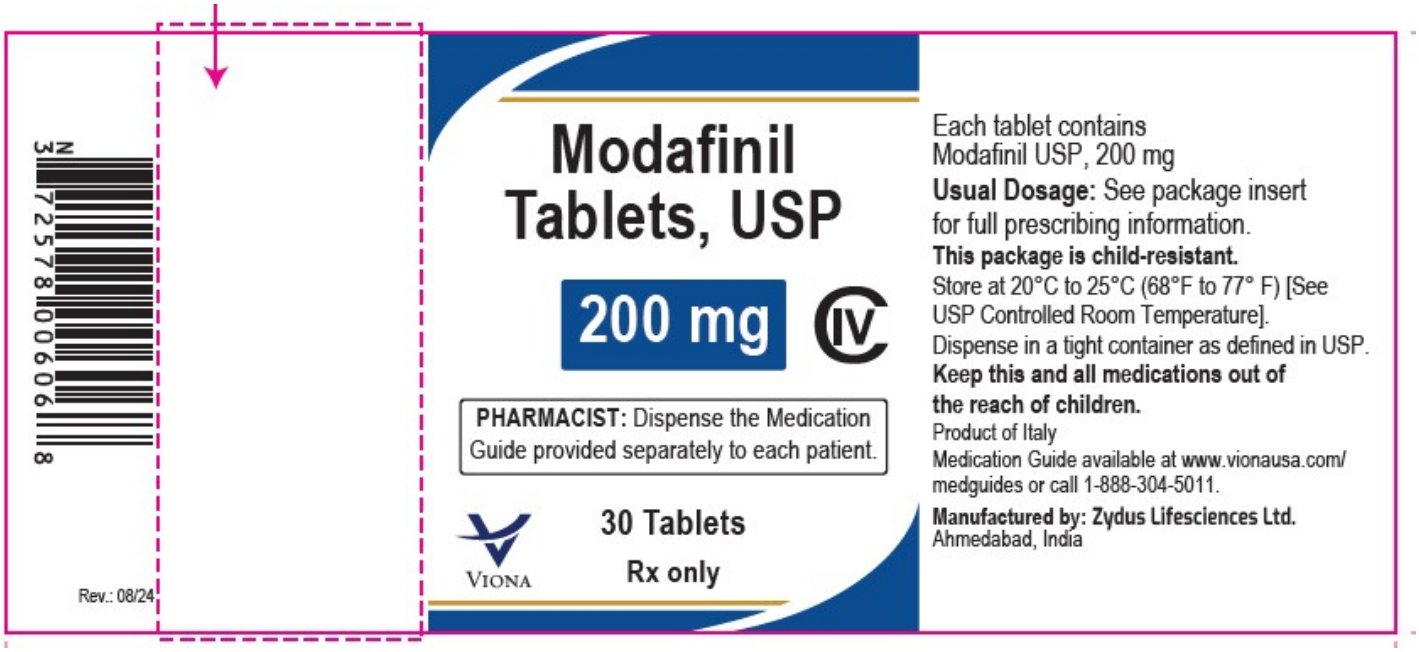


NDC 70771-1052-3

Modafinil Tablets USP, 200 mg

30 Tablets

Rx only



MODAFINIL

modafinil tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1051
Route of Administration	ORAL	**DEA Schedule**	CIV

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MODAFINIL (UNII: R3UK8X3U3D) (MODAFINIL - UNII:R3UK8X3U3D)	MODAFINIL	100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	WHITE (OFF-WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	13mm
Flavor		**Imprint Code**	1072
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1051-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
2	NDC:70771-1051-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
3	NDC:70771-1051-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209966	01/04/2018	

MODAFINIL

modafinil tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1052
Route of Administration	ORAL	**DEA Schedule**	CIV

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MODAFINIL (UNII: R3UK8X3U3D) (MODAFINIL - UNII:R3UK8X3U3D)	MODAFINIL	200 mg

Inactive Ingredients	
Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	WHITE (OFF-WHITE)	**Score**	2 pieces
Shape	CAPSULE (CAPSULE)	**Size**	16mm
Flavor		**Imprint Code**	10;73
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1052-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
2	NDC:70771-1052-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
3	NDC:70771-1052-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209966	01/04/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1051, 70771-1052) , MANUFACTURE(70771-1051, 70771-1052)

Revised: 8/2024 Zydus Lifesciences Limited