

**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

3 N  
7 2 5 7 8 0 0 6 0 6  
8

Rev.: 08/24

**Modafinil  
Tablets, USP**

**200 mg** **IV**

**PHARMACIST:** Dispense the Medication Guide provided separately to each patient.

**30 Tablets**  
**Rx only**

**VIONA**

Each tablet contains Modafinil USP, 200 mg  
**Usual Dosage:** See package insert for full prescribing information.  
**This package is child-resistant.**  
 Store at 20°C to 25°C (68°F to 77° F) [See USP Controlled Room Temperature].  
 Dispense in a tight container as defined in USP.  
**Keep this and all medications out of the reach of children.**  
 Product of Italy  
 Medication Guide available at [www.vionausa.com/medguides](http://www.vionausa.com/medguides) or call 1-888-304-5011.  
**Manufactured by: Zydus Lifesciences Ltd.**  
 Ahmedabad, India

## MODAFINIL

modafinil tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1051
<b>Route of Administration</b>	ORAL	<b>DEA Schedule</b>	CIV

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MODAFINIL</b> (UNII: R3UK8X3U3D) (MODAFINIL - UNII:R3UK8X3U3D)	MODAFINIL	100 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

### Product Characteristics

<b>Color</b>	WHITE (OFF-WHITE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	1072
<b>Contains</b>			

## 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)	
CROSCARMELOSE 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