

NAPROXEN- naproxen tablet
Zydus Lifesciences Limited

NAPROXEN TABLETS

Manufactured by:

Cadila Healthcare Ltd.
India

SPL MEDGUIDE

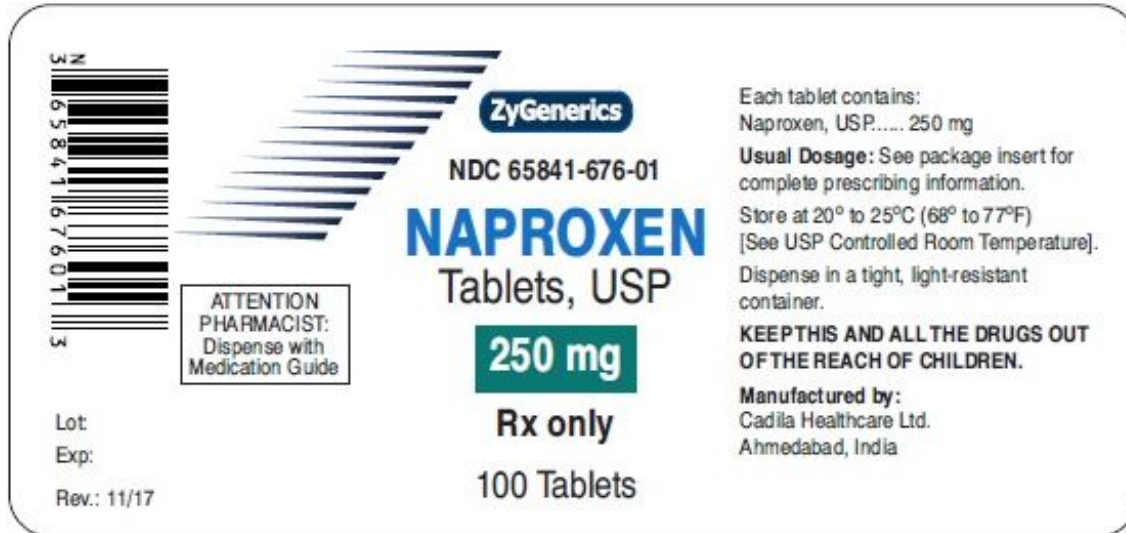
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-676-01

Naproxen tablets, 250 mg

100 Tablets

Rx only



NDC 65841-677-01

Naproxen tablets, 375 mg

100 Tablets

Rx only

**ATTENTION
PHARMACIST:**
Dispense with
Medication Guide

Lot:
Exp:
Rev.: 11/17

ZyGenerics

NDC 65841-677-01

NAPROXEN
Tablets, USP

375 mg

Rx only

100 Tablets

Each tablet contains:
Naproxen, USP..... 375 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container.

**KEEP THIS AND ALL THE DRUGS OUT
OF THE REACH OF CHILDREN.**

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

NDC 65841-678-01

Naproxen tablets, 500 mg

100 Tablets

Rx only

**ATTENTION
PHARMACIST:**
Dispense with
Medication Guide

Lot:
Exp:
Rev.: 11/17

ZyGenerics

NDC 65841-678-01

NAPROXEN
Tablets, USP

500 mg

Rx only

100 Tablets

Each tablet contains:
Naproxen, USP..... 500 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container.

**KEEP THIS AND ALL THE DRUGS OUT
OF THE REACH OF CHILDREN.**

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

NAPROXEN

naproxen tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-676
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
NAPROXEN (UNII: 57Y76R9ATQ) (NAPROXEN - UNII:57Y76R9ATQ)			NAPROXEN	250 mg
Inactive Ingredients				
Ingredient Name				Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POVIDONE (UNII: FZ989GH94E)				
Product Characteristics				
Color		YELLOW	Score	2 pieces
Shape		ROUND	Size	10mm
Flavor			Imprint Code	ZE10
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-676-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2017	
2	NDC:65841-676-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2017	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA078620	11/09/2017	

NAPROXEN			
naproxen tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-677
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
NAPROXEN (UNII: 57Y76R9ATQ) (NAPROXEN - UNII:57Y76R9ATQ)		NAPROXEN	375 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	YELLOW (yellow)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	ZE9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-677-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2017	
2	NDC:65841-677-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2017	
3	NDC:65841-677-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078620	11/09/2017	

NAPROXEN

naproxen tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-678
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPROXEN (UNII: 57Y76R9ATQ) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
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CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POVIDONE (UNII: FZ989GH94E)				
Product Characteristics				
Color	YELLOW	Score	2 pieces	
Shape	CAPSULE	Size	16mm	
Flavor		Imprint Code	ZE8	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-678-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2017	
2	NDC:65841-678-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2017	
3	NDC:65841-678-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA078620		11/09/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-676, 65841-677, 65841-678) , MANUFACTURE(65841-676, 65841-677, 65841-678)

Revised: 9/2023

Zydus Lifesciences Limited