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#### **Caplets**

**Drug Facts** 

## Active ingredient (in each caplet)

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID) <sup>1</sup>

1 nonsteroidal anti-inflammatory drug

# **Purposes**

Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
  - minor pain of arthritis
  - muscular aches
  - backache
  - menstrual cramps
  - headache
  - toothache
  - the common cold
- temporarily reduces fever

#### **Directions**

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older	<ul> <li>take 1 caplet every 8 to 12 hours while symptoms last</li> <li>for the first dose you may take 2 caplets within the first hour</li> <li>do not exceed 2 caplets in any 8- to 12-hour period</li> <li>do not exceed 3 caplets in a 24-hour period</li> </ul>
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#### Other information

- each caplet contains: sodium 20 mg
- store at 20-25 ° C (68-77 ° F). Avoid high humidity and excessive heat above 40 ° C (104 ° F).

#### Inactive ingredients

FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

#### Questions or comments?

**1-800-395-0689** (Mon - Fri 9AM - 5PM EST)

Dist. by:

Bayer Healthcare LLC

Whippany, NJ 07981

In case of overdose, get medical help or contact a Poison Control Center right away.

#### PRINCIPAL DISPLAY PANEL - 24 Caplet Bottle Carton

**ALL DAY STRONG ®** 

**ALEVE**<sub>®</sub>

naproxen sodium tablets, 220 mg (NSAID)

Pain reliever/fever reducer

STRENGTH TO LAST 12 HOURS
ACTUAL SIZE
24 CAPLETS

CAPSULE-SHAPED TABLETS



### **ALEVE CAPLETS**

naproxen sodium tablet

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Proc	luct	Information	

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0280-6000

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
NADROVEN CODUM (UNIII OTNOTCOACC) (NADROVEN LINII ETYTCOATO)	NADDOVENI CODILINA	220

NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)

NAPROXEN SODIUM | 220 mg

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Inactive	<b>Ingredients</b>
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Ingredient Name	Strength

POVIDONE (UNII: FZ989GH94E)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL (capsule shaped tablets)	Size	12mm	
Flavor		Imprint Code	Aleve	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280- 6000-06	1 in 1 CARTON	02/26/2014	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0280- 6000-24	1 in 1 CARTON	02/26/2014	
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0280- 6000-50	1 in 1 CARTON	02/26/2014	
3		50 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0280- 6000-10	1 in 1 CARTON	02/26/2014	06/30/2022
4		100 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0280- 6000-15	1 in 1 CARTON	02/26/2014	07/31/2020
5		150 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0280- 6000-02	1 in 1 CARTON	03/26/2014	
6		200 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0280- 6000-27	270 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2021	
8	NDC:0280- 6000-32	1 in 1 CARTON	02/26/2014	
8		320 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:0280- 6000-70	1 in 1 CARTON	03/18/2016	
9		150 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:0280- 6000-75	1 in 1 CARTON	03/18/2016	01/30/2020
10		180 in 1 BOTTLE; Type 0: Not a Combination Product		

11	NDC:0280- 6000-01	24 in 1 BOTTLE; Type 0: Not a Combination Product	02/26/2014	
12	NDC:0280- 6000-03	1 in 1 CARTON	02/26/2014	
12		130 in 1 BOTTLE; Type 0: Not a Combination Product		
13	NDC:0280- 6000-04	1 in 1 CARTON	02/26/2014	
13		225 in 1 BOTTLE; Type 0: Not a Combination Product		
14	NDC:0280- 6000-05	1 in 1 CARTON	02/26/2014	
14		36 in 1 BOTTLE; Type 0: Not a Combination Product		
15	NDC:0280- 6000-07	48 in 1 POUCH; Type 0: Not a Combination Product	02/26/2014	
16	NDC:0280- 6000-08	1 in 1 CARTON	02/26/2014	
16		65 in 1 BOTTLE; Type 0: Not a Combination Product		
17	NDC:0280- 6000-12	1 in 1 CARTON	07/01/2021	
17		90 in 1 BOTTLE; Type 0: Not a Combination Product		
18	NDC:0280- 6000-09	1 in 1 POUCH; Type 0: Not a Combination Product	07/01/2020	
19	NDC:0280- 6000-16	1 in 1 POUCH; Type 0: Not a Combination Product	07/01/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020204	02/26/2014	

# Labeler - Bayer HealthCare LLC. (112117283)

Revised: 10/2022 Bayer HealthCare LLC.