## ALEVE GELCAPS- naproxen sodium tablet, coated Bayer HealthCare LLC.

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Aleve ®

Gelcaps

**Drug Facts** 

#### Active ingredient (in each tablet)

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

1 nonsteroidal anti-inflammatory drug

#### **Purpose**

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

- take 1 tablet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 tablets within the first hour
- do not exceed 2 tablets in any 8- to 12hour period
- do not exceed 3 tablets in a 24-hour period

#### Other information

- each tablet 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**

D&C yellow #10 aluminum lake, edetate disodium, edible ink, FD&C blue #1, FD&C yellow #6 aluminum lake, gelatin, glycerin, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, stearic acid, talc, titanium dioxide

#### Questions or comments?

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

Dist. by:

Bayer Healthcare LLC

Whippany, NJ 07981

#### PRINCIPAL DISPLAY PANEL



### SOFT GRIP® ARTHRITIS CAP ALL DAY STRONG®

#### **ALEVE**®

naproxen sodium tablets, 220 mg (NSAID)

Pain reliever/fever reducer

THIS PACKAGE IS

**CHILD-RESISTANT** 

**STRENGTH** 

TO LAST

12 HOURS

40 GELCAPS

GELATIN COATED

CAPSULE-SHAPED TABLETS

#### **ALEVE GELCAPS**

naproxen sodium tablet, coated

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0280-6070

**Route of Administration** ORAL

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

Ingredient Name	<b>Basis of Strength</b>	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATO)	NAPROXEN SODIUM	220 ma

Inactive Ingredients	
Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ 989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	yellow	Score	no score	
Shape	OVAL	Size	15mm	
Flavor		Imprint Code	ALEVE	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0280-6070- 40	1 in 1 CARTON	08/01/2002			
1		40 in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
NDA	NDA020204	08/01/2002			

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 11/2023 Bayer HealthCare LLC.