ALEVE- naproxen sodium tablet
Bayer HealthCare LLC.

Aleve ® Tablets UI 1600169

Drug Facts

Active ingredient (in each tablet)

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID) [1]

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	• 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 12-hour period • do not exceed 3 tablets in a 24-hour period
• Children under 12 years	• ask a doctor

Other information

- **each tablet contains:** sodium 20 mg
- store at 20-25ºC (68-77ºF). 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 Tablet Bottle Carton

ALL DAY STRONG®

ALEVE®

naproxen sodium tablets, 220 mg (NSAID)

Pain reliever/fever reducer

STRENGTH TO LAST 12 HOURS

ACTUAL SIZE
24 TABLETS

ALEVE
naproxen sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0280-6010
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	blue (light blue)	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	ALEVE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-6010-24	1 in 1 CARTON	07/26/2002	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0280-6010-50	1 in 1 CARTON	07/26/2002	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0280-6010-01	1 in 1 CARTON	07/26/2002	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0280-6010-02	1 in 1 CARTON	07/26/2002	
4		130 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0280-6010-03	1 in 1 CARTON	07/26/2002	
5		150 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0280-6010-04	1 in 1 CARTON	07/26/2002	
6		36 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0280-6010-	225 in 1 BOTTLE; Type 0: Not a Combination	07/26/2002	

	06	Product	07/26/2002	
8	NDC:0280-6010-05	1 in 1 CARTON	07/26/2002	
8		65 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:0280-6010-07	270 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2002	
10	NDC:0280-6010-09	90 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2002	
11	NDC:0280-6010-10	1 in 1 TRAY	07/26/2002	
11		10 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	07/26/2002	

Labeler - Bayer HealthCare LLC. (112117283)