ALEVE- naproxen sodium tablet tablet
Lil' Drug Store Products, Inc.

ALEVE CAPLETS naproxen sodium tablet

Drug Facts

Active Ingredients(in each caplet)

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

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1 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

Warnings

Allergy alert

Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning

NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor

- you experience any of the following signs of stomach bleeding:
    - feel faint
    - vomit blood
    - have bloody or black stools
    - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
    - chest pain

- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

Keep out of reach of children.

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

If pregnant or breast-feeding,

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen
sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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 caplet every 8 to 12 hours while symptoms last • for the first dose you may take 2 caplets within the first hour • do not exceed 2 caplets in any 8- to 12-hour period • do not exceed 3 caplets in a 24-hour period
Children under 12 years	• ask a doctor

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)

PRINCIPAL DISPLAY PANEL - 220 mg Caplet Pouch Box

ALL DAY STRONG®

ALEVE®

naproxen sodium tablets, 220 mg **(NSAID)**

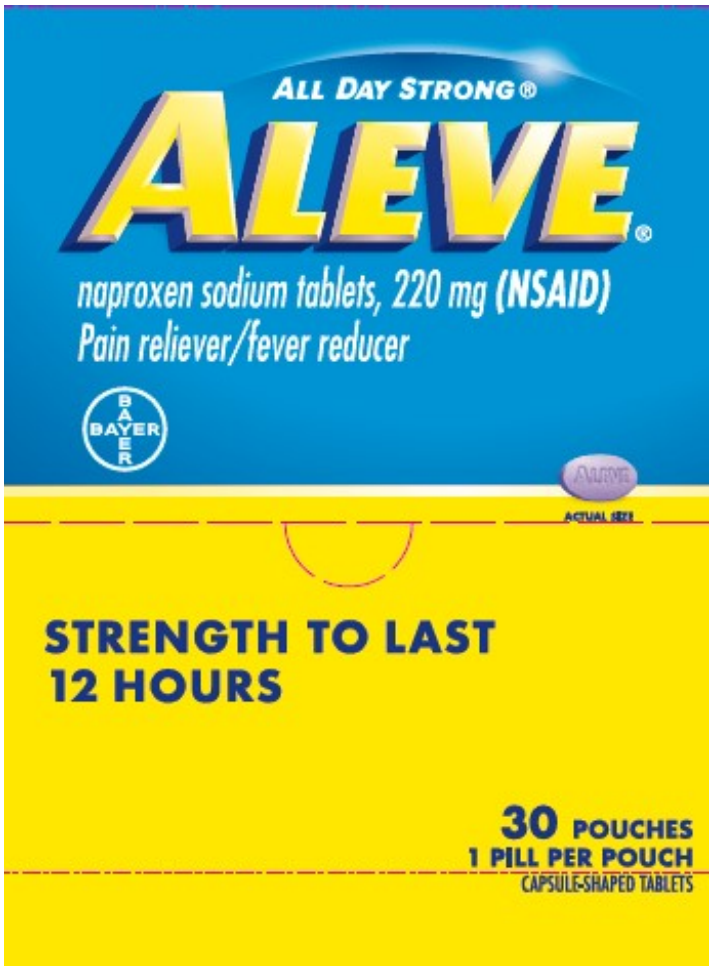
Pain reliever/fever reducer

STRENGTH TO LAST 12 HOURS

30 POUCHES

1 PILL PER POUCH

Capsule-Shaped Tablet



Principal Display Panel- 220 mg 2 Caplet Pouch Package

ALL DAY STRONG®

ALEVE®

naproxen sodium tablets, 220 mg **(NSAID)**

Pain reliever/fever reducer

STRENGTH TO LAST 12 HOURS

2 Caplets

Capsule-Shaped Tablets

PRINCIPAL DISPLAY PANEL- 220 mg 3 Caplet Pouch Package

ALL DAY STRONG®

ALEVE®

naproxen sodium tablets, 220 mg **(NSAID)**

Pain reliever/fever reducer

STRENGTH TO LAST 12 HOURS

3 Caplets

Capsule-Shaped Tablet

Aleve CVP 2 Count Carton

ALL DAY STRONG ®

ALEVE ®

naproxen sodium tablets, 220 mg (NSAID)
Pain reliever/fever reducer

[Bayer Cross]

[tablet image]

ACTUAL SIZE

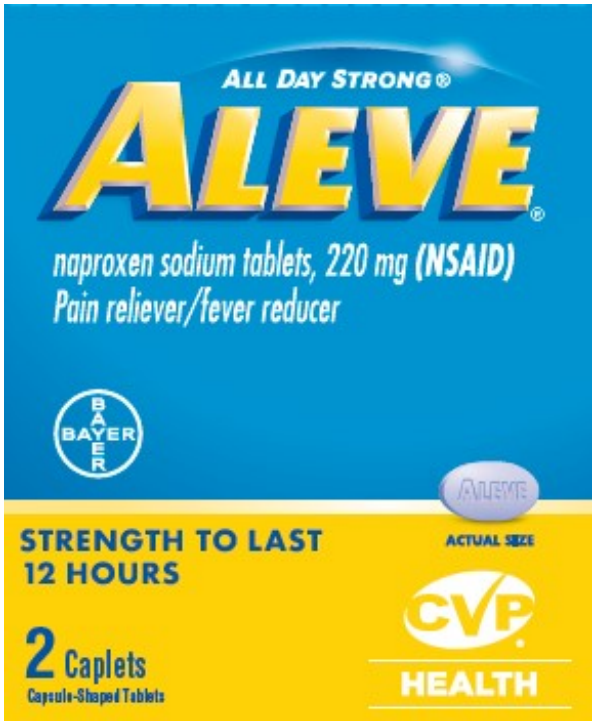
STRENGTH TO LAST

12 HOURS

2 Caplets
Capsule-Shaped Tablets

CVP

HEALTH



ALEVE

naproxen sodium tablet tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:29485-6751
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	200 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	**Score**	no score

Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	Aleve
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29485-6751-6	3 in 1 BLISTER PACK	02/06/2017	09/30/2025
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020204	02/06/2002	09/30/2025

ALEVE

naproxen sodium tablet tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:29485-1013
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	200 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	blue	**Score**	no score

Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	Aleve
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29485-1013-2	2 in 1 BLISTER PACK	04/30/2002	09/30/2025
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020204	04/30/2002	09/30/2025

ALEVE

naproxen sodium tablet tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:29485-7534
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	200 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	Aleve
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29485-7534-3	30 in 1 BOX	11/01/2016	12/31/2025
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020204	11/01/2016	12/31/2025

ALEVE

naproxen sodium tablet tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:29485-6502
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	200 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	Aleve
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29485-6502-4	4 in 1 CARTON	08/25/2017	09/30/2025
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:29485-6502-2	2 in 1 CARTON	09/30/2022	12/31/2025
2		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020204	08/25/2017	12/31/2025

Labeler - Lil' Drug Store Products, Inc. (093103646)

Revised: 12/2023 Lil' Drug Store Products, Inc.