#### ALEVE- naproxen sodium tablet ALEVE, TRAVEL BASIX- naproxen sodium tablet Lil' Drug Store Products, Inc

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Aleve ®

**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

#### 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

#### 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 if

- 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, or kidney disease
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have asthma

#### Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking any other drug

#### When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

#### Stop use and ask a doctor if

- 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
- 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

**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.

#### Keep out of reach of children.

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

#### **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 24hour 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

#### **Ouestions or comments?**

**1-800-395-0689** (Mon-Fri 9AM-5PM EST) or www.aleve.com

## PRINCIPAL DISPLAY PANEL - 220 mg Caplet Pouch Carton, Lil' Drug Store 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

3 Caplets Capsule-Shaped Tablets

[Lil' DrugStore ® logo]



# Aleve 2ct, CVP HEALTH - PDP/Package 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** logo]



# Aleve 2ct, TRAVEL BASIX - PDP/Package ALL DAY STRONG $^{\circledR}$ 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

[TRAVEL BASIX logo]



#### **ALEVE**

naproxen sodium tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-9702	
Route of Administration	ORAL			

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

Inactive Ingredients				
Ingredient Name	Strength			
ALUMINUM OXIDE (UNII: LMI26O6933)				
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)				
TALC (UNII: 7SEV7J4R1U)				

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

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

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:66715- 9702-1	1 in 1 CARTON	01/01/2000	06/28/2024			
1		1 in 1 POUCH; Type 0: Not a Combination Product					
2	NDC:66715- 9702-2	2 in 1 CARTON	01/01/2000				
2		1 in 1 POUCH; Type 0: Not a Combination Product					
3	NDC:66715- 9702-3	3 in 1 CARTON	01/01/2000				
3		1 in 1 POUCH; Type 0: Not a Combination Product					
4	NDC:66715- 9702-0	30 in 1 CARTON	02/03/2011	02/03/2011			
4		1 in 1 POUCH; Type 0: Not a Combination Product					

Marketing Information					
Marketing Application Number or Monograph Marketing Start Marketing E Category Citation Date Date					
NDA	NDA020204	01/01/2000			

### **ALEVE**

naproxen sodium tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-6502	
Route of Administration	ORAL			

Active Ingredient/Active Moiety					
Ingredient Name	<b>Basis of Strength</b>	Strength			
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg			

Inactive Ingredients	
Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:66715- 6502-2	2 in 1 CARTON	05/06/2022				
1		1 in 1 POUCH; Type 0: Not a Combination Product					

Marketing Information					
Marketing Application Number or Monograph Marketing Start Marketing Enc Category Citation Date Date					
NDA	NDA020204	05/06/2022			

## ALEVE, TRAVEL BASIX

naproxen sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-6411
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg

Inactive Ingredients			
Ingredient Name	Strength		
ALUMINUM OXIDE (UNII: LMI26O6933)			
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

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

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:66715- 6411-2	2 in 1 CARTON	11/15/2022			
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	11/15/2022	

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

Revised: 10/2023 Lil' Drug Store Products, Inc