

**ALL DAY PAIN RELIEF- naproxen sodium tablet**  
**Cardinal Health (Leader) 49781**

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**Drug Facts**

**Active ingredient (in each tablet)**

**Naproxen sodium 220 mg**

**(naproxen 200 mg) (NSAID)\***

**\*nonsteroidal anti-inflammatory drug**

**Purposes**

**Pain reliever/fever reducer**

**Uses**

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - minor pain of arthritis
  - toothache
  - backache
  - the common cold
  - menstrual cramps
- 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
- have 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- 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 have problems or serious side effects from taking pain relievers or fever reducers
- you have asthma
- you are taking a diuretic

**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
  - have bloody or black stools
  - vomit blood
  - 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
- redness or swelling is present in the painful area
- any new symptoms appear
- you have difficulty swallowing
- it feels like the pill is stuck in your throat

**If pregnant or breast-feeding,**

ask a health professional before use. It is especially important not to use naproxen sodium during the last 3 months of 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 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 caplet contains: **sodium 20 mg**
- store at 20° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F).
- read all warnings and directions before use.

### **Inactive ingredients**

FD&C blue #2 aluminum lake, hypromellose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, povidone k-30, sodium starch glycolate, stearic acid, titanium dioxide

### **Questions or comments?**

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

### **Principal Display Panel**

Compare to ALEVE® active ingredient†

EASY OPEN CAP

NOT FOR HOUSEHOLDS WITH YOUNG CHILDREN

**All Day**

### **Pain Relief**

Naproxen Sodium Tablets, 220 mg

Pain reliever/fever reducer (NSAID)

Tablets

DO NOT USE IF INNER SEAL UNDER BOTTLE CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.

†This product is not manufactured or distributed by Bayer Healthcare, LLC., owner of the registered trademark Aleve®.

DISTRIBUTED BY: CARDINAL HEALTH

DUBLIN, OHIO 43017

[www.myleader.com](http://www.myleader.com)

1-800-200-6313

Product of India

### **Product Label**

NDC 49781-101-56

**EASY OPEN CAP**

NOT FOR HOUSEHOLDS WITH YOUNG CHILDREN

**LEADER®**

**All Day Pain Relief**

**Naproxen Sodium Tablets, 220 mg**

Pain Reliever/Fever Reducer (NSAID)

**200 TABLETS** Actual Size

**SATISFACTION GUARANTEED**

Compare to **ALEVE®** active ingredient†

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**Drug Facts**

**Active ingredient (in each tablet)**  
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**Pain reliever/fever reducer**

**Uses** ■ temporarily relieves minor aches and pains due to: ■ headache ■ muscular aches ■ minor pain of arthritis ■ toothache ■ backache ■ the common cold ■ menstrual cramps ■ 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) ■ skin redness ■ rash ■ blisters ■ an allergic reaction occurs, stop use and seek medical help right away.

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**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 have problems or serious side effects from taking pain relievers or fever reducers ■ you have asthma ■ you are taking a diuretic

**Drug Facts (continued under label)**

DISTRIBUTED BY: CARDINAL HEALTH  
 DUBLIN, OHIO 43017  
 www.myleader.com 1-800-200-6313  
 CIN 4991147

All Leader® Brand Products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

PLD-A203A LB001635 Product of India

Lot No.:  
 Exp. Date:

0 96295 12627 3

**Drug Facts (continued)**

**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 ■ have bloody or black stools ■ vomit blood ■ 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 ■ redness or swelling is present in the painful area ■ any new symptoms appear ■ you have difficulty swallowing ■ it feels like the pill is stuck in your throat

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**Other information** ■ each tablet contains: sodium 20 mg ■ store at 20° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F). ■ read all warnings and directions before use.

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**Questions or comments?**  
 Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

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**Leader All Day Pain Relief Tablets**

<b>ALL DAY PAIN RELIEF</b>			
naproxen sodium tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49781-101
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg	
<b>Inactive Ingredients</b>			

Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

Color	BLUE	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	220
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49781-101-50	1 in 1 BOX	07/31/2014	07/31/2020
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:49781-101-51	1 in 1 BOX	07/31/2014	07/31/2020
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:49781-101-56	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/31/2014	07/31/2020

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	07/31/2014	07/31/2020

**Labeler** - Cardinal Health (Leader) 49781 (097537435)