NAPROXEN SODIUM- naproxen sodium tablet
Cardinal Health (Leader) 49781

Drug Facts

Active ingredient (in each caplet)

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.(1-800-222-1222)

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 20º to 25ºC (68º to 77ºF). Avoid high humidity and excessive heat above 40ºC (104ºF).
- read all warnings and directions before use. Keep carton.

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†

All Day Pain Relief

Naproxen Sodium Tablets, 220 mg

Pain Reliever/Fever Reducer (NSAID)

Caplets**

**Capsule-Shaped Tablets

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

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY: CARDINAL HEALTH

DUBLIN, OHIO 43017

CIN 4991139

www.myleader.com

1-800-200-6313

Product of India

Product Label

NDC 49781-100-56

LEADER®

Compare to ALEVE® active ingredient*

All Day Pain Relief

Naproxen Sodium Tablets, 220 mg

Pain Reliever/Fever Reducer (NSAID)

SATISFACTION GUARANTEED

Caplets

200 CAPLETS** (**Capsule-Shaped Tablets)

Actual Size

NDC 49781-100-56

LEADER®

Compare to ALEVE® active ingredient*

All Day Pain Relief

Naproxen Sodium Tablets, 220 mg

Pain Reliever/Fever Reducer (NSAID)

SATISFACTION GUARANTEED

Caplets

200 CAPLETS** (**Capsule-Shaped Tablets)

Actual Size

v60x4

10088005

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Drug Facts (continued)

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1-800-200-6313

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0 96295 12626 6

PLD-A202A FC001994 Product of India

Lot No.:

Exp. Date:

Leader All Day Pain Relief Caplets

NAPROXEN SODIUM

naproxen sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49781-100
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**
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
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	CAPSULE	**Size**	12mm
Flavor		**Imprint Code**	220
Contains			

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

2	51	1 in 1 BOX	07/31/2014	07/31/2020
3		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

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)

Revised: 7/2019 Cardinal Health (Leader) 49781