ALL DAY PAIN RELIEF- 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.

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

- ea**ch 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. Keep carton.

Inactive ingredients

croscarmellose sodium, FD&C blue #2, macrogol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, talc, titanium dioxide

Questions or comments?

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

Principal Display Panel

All Day Pain Relief

Naproxen Sodium Tablets, 220 mg

Pain Reliever / Fever Reducer **(NSAID)**

CAPLETS**

(**Capsule-Shaped Tablets)

220 mg each

Compare to the active ingredient in Aleve®†

†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 PRINTED 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

www.myleader.com

1-800-200-6313

Product Label

Leader All Day Pain Relief Caplets

ALL DAY PAIN RELIEF

naproxen sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49781-146
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**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BLUE	**Score**	no score
Shape	CAPSULE	**Size**	12mm
Flavor		**Imprint Code**	I7
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49781-146-51	1 in 1 BOX	11/30/2015	02/01/2022
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:49781-146-50	1 in 1 BOX	11/30/2015	02/01/2022
2		50 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	ANDA079096	11/30/2015	02/01/2022

Labeler - Cardinal Health (Leader) 49781 (097537435)