

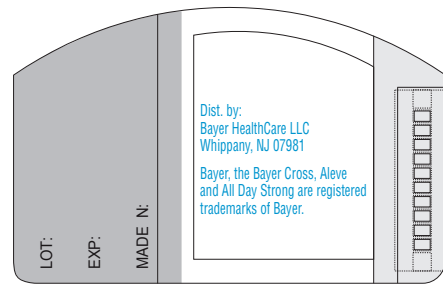
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FDA00215-7

DRUG FACTS INFO		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	8.5 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings <sup>†</sup>	8 pt.-bold italic <sup>†</sup>	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	5 pt.
Leading	≥0.5 pt.	6 & 6.5 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Bar lines <sup>†</sup>	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

<sup>†</sup> Headings are to be at least 2pts larger than Body Text.  
<sup>\*\*</sup> Drug Facts Title to be larger than a 1 other type size used in ODP  
<sup>†</sup> FDA Recommends 2.5pt rule

**Drug Facts (continued)**

**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)
- skin redness
- skin 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 thinner (anticoagulant) or steroid drug
- take other drugs containing 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 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, 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 if you are**

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

**When using this product**

- take with food or milk, if stomach upset occurs

**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

**Drug Facts (continued)**

- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness in one part or side of body
  - slored speech
  - leg swelling
  - joint gets worse or lasts more than 10 days
  - new gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- rashes 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 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
- ask a doctor

Children under 12 years

**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**

FDAC blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, lac, titanium dioxide

**Questions or comments?**

1-800-368-0888 (Mon-Fri 9AM - 5PM EST)

Bayer

**Drug Facts**

**Active ingredient (in each caplet):** Naproxen sodium, 220 mg (naproxen 20 mg) (NSAID).....Pain reliever/fever reducer/ nonsteroidal anti-inflammatory drug

**Do not use if printed safety seal bearing Bayer HealthCare water cap is torn or missing.**

**Keep out of reach of children.**