



**Actual Size 100%**

FDA 56535-1

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN PKT
Drug Facts Table	> 8 pt. <sup>44</sup>	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings*	9 pt.-bold italic <sup>45</sup>	8 pt.
Subheadings	> 6 pt.	6 pt.
Body Text	> 6 pt.	6 pt.
Tables	5 pt.	12 pt.
Equations	> 0.5 pt.	6.5 - 6.8 pt.
Headlines	0.5 pt. min.	0.5 pt.
Box and Berlines†	> 0.5 pt. min.	2.5 pt.
Characterist. Per Inch	No more than 391	< 391

\* If the font size is less than 8 pt. for the body text, the font size shall be at least 6 pt. for the box and berlines and 2.5 pt. for the headlines.  
† If the font size is less than 2.5 pt. for the box and berlines, the font size shall be at least 2.5 pt.

**Drug Facts (continued)**

**Stop use and ask a doctor if**

- you experience any of the following signs of stomach bleeding:
- feel faint
- have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling
- redness or swelling is present in the painful area

any new symptoms appear

- fever gets worse or lasts more than 3 days
- you have difficulty swallowing or the caplet feels stuck in your throat
- you get nervous, dizzy, or sleepless
- nasal congestion lasts more than 7 days

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 otherwise 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.

**Drug Facts (continued)**

**Directions**

- do not take more than directed
- swallow whole; do not crush or chew
- drink a full glass of water with each dose
- adults and children 12 years and older: 1 caplet every 12 hours; do not take more than 2 caplets in 24 hours
- children under 12 years: do not use

**Other information**

- each caplet contains: sodium 22 mg
- store at 20°-25°C (68°-77°F)
- store in a dry place

**Inactive ingredients** colloidal silicon dioxide, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

**Questions or comments?** 1-800-986-0369 (Mon-Fri 9AM - 5PM EST)

**Drug Facts (continued)**

**Purposes**

Pain reliever- fever reducer  
nasal decongestant

**Active ingredients (in each caplet)**

Naproxen sodium 220 mg (NSAID)  
Pain reliever- fever reducer  
Pseudoephedrine HCl 120 mg extended-release  
Nasal decongestant

**Uses**

temporarily relieves these cold, sinus, and flu symptoms: nasal and sinus congestion (promotes sinus drainage and restores free breathing through the nose)

- sinus pressure
- minor body aches and pains
- nasal and sinus congestion (promotes sinus drainage and restores free breathing through the nose)

**Warnings**

**Warning:** Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- skin redness
- asthma (wheezing)
- rash
- diarrhea

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

**When using this product**

- take with food or milk if stomach upset occurs
- take any other drug
- may decrease the benefit of aspirin
- take aspirin for heart attack or stroke, because naproxen may under a doctor's care for any serious condition
- under a doctor's care for any serious condition
- relieves or fever reducers

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

- you have problems or serious side effects from taking pain relievers or fever reducers
- you are taking a diuretic
- urinary due to an enlarged prostate gland, or had a stroke
- kidney disease, asthma, thyroid disease, diabetes, have trouble
- you have high blood pressure, heart disease, liver cirrhosis, or
- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn or inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug, ask a doctor or pharmacist before taking this product.
- in children under 12 years of age

**Do not use**

- if you have ever had an allergic reaction to any other pain reliever- fever reducer
- right before or after heart surgery
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug, ask a doctor or pharmacist before taking this product.

**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.

**Drug Facts (continued)**