

Example Drug Facts Label for Naproxen Sodium 220 mg in a Tablet/Caplet/Gelcap Dosage Form

---

**Drug Facts**

---

<b>Active ingredient (in each [insert dosage unit])</b>	<b>Purposes</b>
Naproxen sodium 220 mg (naproxen 200 mg).....	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 which may include:  
# hives    # facial swelling    # asthma (wheezing)    # shock

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take naproxen sodium or other pain relievers/fever reducers.  
Naproxen sodium may cause stomach bleeding.

---

**Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer

---

**Ask a doctor before use if you have** ever had serious side effects from any pain reliever or fever reducer

---

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

- # under a doctor's care for any serious condition
  - # taking any other drug
  - # taking any other product that contains naproxen sodium, or any other pain reliever/fever reducer
- 

**Stop use and ask a doctor if**

- # an allergic reaction occurs. Seek medical help right away.
- # pain gets worse or lasts more than 10 days
- # fever gets worse or lasts more than 3 days
- # you have difficulty swallowing
- # it feels like the pill is stuck in your throat
- # you develop heartburn
- # stomach pain occurs or lasts, even if symptoms are mild

- # redness 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

# drink a full glass of water with each dose

Adults and children 12 years and older	<ul style="list-style-type: none"> <li># take 1 [insert dosage unit] every 8 to 12 hours while symptoms last</li> <li># first dose - you may take 2 [insert dosage unit(s)] within the first hour</li> <li># the smallest effective dose should be used</li> <li># do not exceed 2 [insert dosage unit(s)] in any 8- to 12-hour period</li> <li># do not exceed 3 [insert dosage unit(s)] in a 24-hour period</li> </ul>
Adults over 65 years	<ul style="list-style-type: none"> <li># do not take more than 1 [insert dosage unit] every 12 hours unless directed by a doctor</li> </ul>
Children under 12 years	<ul style="list-style-type: none"> <li># ask a doctor</li> </ul>

**Other information**

# each [insert dosage unit] contains: sodium 20 mg

# optional - tamper evident statement

# store at 20-25° C (68-77° F). Avoid high humidity and excessive heat above 40° C (104° F)

# optional - see [end or side] panel for lot number and expiration date

**Inactive ingredients** [list ingredients in alphabetical order]

**Questions or comments?** call toll free 1-800-XXX-XXXX

NOTE: The **Drug Facts (continued)** title should appear wherever the labeling continues onto another panel of the package.