

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

Drug Facts

Active ingredient (in each [insert dosage unit]) **Purposes**
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
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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
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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	# take 1 [insert dosage unit] every 8 to 12 hours while symptoms last # first dose - you may take 2 [insert dosage unit] within the first hour # the smallest effective dose should be used # do not exceed 2 [insert dosage unit] in any 8- to 12-hour period # do not exceed 3 [insert dosage unit] in a 24-hour period
Adults over 65 years	# do not take more than 1 [insert dosage unit] every 12 hours unless directed by a doctor
Children under 12 years	# ask a doctor

Other information

each [insert dosage unit] contains: sodium 20 mg

optional - tamper evident statement

store at 20-25⁰ C (68-77⁰ F). Avoid high humidity and excessive heat above 40⁰ C (104⁰ 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.