

Example Drug Facts Label for Ibuprofen 200 mg in a Tablet/Capsule Dosage Form

Drug Facts

Active ingredient (in each [insert dosage unit])	Purposes
Ibuprofen 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: Ibuprofen 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 ibuprofen or other pain relievers/fever reducers. Ibuprofen 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

- # stomach pain
 - # 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 any other drug
 - # taking any other product that contains ibuprofen, or any other pain reliever/fever reducer
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When using this product take with food or milk if stomach upset occurs

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
 - # stomach pain or upset gets worse or lasts
 - # redness or swelling is present in the painful area
 - # any new symptoms appear
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If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen 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.

Directions¹

do not take more than directed

adults and children 12 years and older:

take 1 [insert dosage unit] every 4 to 6 hours while symptoms persist

if pain or fever does not respond to 1 [insert dosage unit], 2 [insert dosage unit(s)] may be used

do not exceed 6 [insert dosage unit(s)] in 24 hours, unless directed by a doctor

the smallest effective dose should be used

children under 12 years: ask a doctor

Other information

optional - tamper evident statement

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

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.

¹The information for the two age groups may be presented in a table format in accord with 21 CFR 201.66(d)(9) with the **do not take more than directed** statement appearing above the top line of the table.