

## SECTION IV: CURRENT OTC ANALGESIC LABELING

This section contains the currently available labeling for acetaminophen, aspirin, ibuprofen, naproxen, and ketoprofen. It also includes the recently proposed labeling for ibuprofen published in a proposed rule on August 21, 2002. The table below provides the specific drug and the rulemaking or guidance document from which the labels were obtained.

	<b>Drug</b>	<b>Source</b>
<b>A.</b>	<b>Acetaminophen</b>	<b>Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Drug Use; Tentative Final Monograph - Proposed Rule 1998</b>
<b>B.</b>	<b>Aspirin</b>	<b>Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Drug Use; Tentative Final Monograph - Proposed Rule 1998</b>
<b>C.</b>	<b>Ibuprofen</b>	<b>Guidance for Industry: Labeling OTC Human Drug; Products Updating Labeling in ANDAs (February 2001)</b>
<b>D.</b>	<b>Naproxen</b>	<b>Guidance for Industry: Labeling OTC Human Drug; Products Updating Labeling in ANDAs (February 2001)</b>
<b>E.</b>	<b>Ketoprofen</b>	<b>Example of NDA Currently Approved Labeling</b>
<b>F.</b>	<b>Ibuprofen</b>	<b>Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Drug Use; Proposed Amendment of the Tentative Final Monograph (August 21, 2002)</b>

**A**

## ***Drug Facts***

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**Active ingredients (in each caplet)**

Acetaminophen 325 mg

**Purpose**

Pain reliever/fever reducer

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**Uses** ■ temporarily relieves minor aches and pains due to:

- a cold
  - headache
  - toothache
  - muscular aches
  - backache
  - premenstrual cramps or menstrual cramps
  - minor arthritis pain
  - temporarily reduces fever
- 

**Warnings**

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

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**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 days
  - fever gets worse or lasts more than 3 days
  - redness or swelling is present in the painful area
  - any new symptoms appear
- 

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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**Directions**

- adults and children 12 years and older
    - 1 to 2 caplets every 4 hours while symptoms persist
    - do not exceed 12 caplets in 24 hours
    - use as directed above or as directed by a doctor
  - children under 12 years: ask a doctor
- 

**Other information**

- **each caplet contains:** *[insert applicable ingredient(s) (such as sodium and/or calcium), and number of milligrams]*
  - store at 20 - 25°C (68 - 77°F)
  - *[add tamper-evident statement here]*
- 

**Inactive ingredients (list in alphabetical order)**

**Questions or comments?** *(list toll-free phone number) or (list web address) (may include the days of the week and times of the day when a person is available to respond to questions)*

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[Please note: The font size, spacing, bolding, and formatting in this label are not necessarily compliant with §201.66]

**B**

## ***Drug Facts***

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***Active ingredients (in each caplet)***

Aspirin 325 mg

***Purpose***

Pain reliever/fever reducer

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***Uses*** ■ temporarily relieves minor aches and pains due to:

- a cold
  - headache
  - toothache
  - muscular aches
  - backache
  - premenstrual cramps and menstrual cramps
  - minor arthritis pain
  - temporarily reduces fever
- 

### ***Warnings***

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox, flu symptoms, or flu should NOT use this product. If nausea, vomiting, or fever occur, consult a doctor because these symptoms could be an early sign of Reye syndrome, a rare but serious illness

**Allergy alert:** Aspirin 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 aspirin or other pain relievers/fever reducers. Aspirin may cause stomach bleeding.

**IMPORTANT:** See your doctor before taking this product for your heart or for other new uses of aspirin, because serious side effects could occur with self-treatment.

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

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**Ask a doctor before use if you have**

- asthma
  - ulcers
  - bleeding problems
  - stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain
- 

**Ask a doctor or pharmacist before use if you are taking a prescription drug for:**

- anticoagulation (thinning of the blood)
  - diabetes
  - gout
  - arthritis
- 

**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
  - redness or swelling is present in the painful area
  - any new symptoms appear
  - ringing in the ears or loss of hearing occurs
- 

**If pregnant or breast-feeding,** ask a health professional before use. It is especially important not to use aspirin 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.

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### ***Directions***

- adults and children 12 years and older
  - 1 to 2 caplets every 4 hours while symptoms persist
  - drink a full glass of water with each dose
  - do not exceed 12 caplets in 24 hours
  - use as directed above or as directed by a doctor

- children under 12 years: ask a doctor

***Other information***

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■ **each caplet contains:** *[insert applicable ingredient(s) (such as sodium and/or calcium), and number of milligrams]*

- store at 20 - 25°C (68 - 77°F)

■ *[add tamper-evident statement here]*

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***Inactive ingredients (list in alphabetical order)***

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***Questions or comments? (list toll-free phone number) or (list web address) (may include the days of the week and times of the day when a person is available to respond to questions)***

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**C**

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

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**Drug Facts**

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<b>Active ingredient (in each [insert dosage unit])</b>	<b>Purposes</b>
ibuprofen 200 mg.....	Pain reliever/fever reducer

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**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.

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

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**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
- 

**When using this product** take with food or milk if stomach upset occurs

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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
  - stomach pain or upset gets worse or lasts
  - 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 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.

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***Directions***<sup>3</sup>

- **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 20-25° 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]

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

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

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<sup>3</sup>The information for the two age groups can 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.

**D**

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

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**Drug Facts**

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<b>Active ingredient (in each [insert dosage unit])</b>	<b>Purposes</b>
Naproxen sodium 220 mg (naproxen 200 mg).....	Pain reliever/fever reducer

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**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.

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

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

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**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.

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**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] within the first hour</li> <li>■ the smallest effective dose should be used</li> <li>■ do not exceed 2 [insert dosage unit] in any 8- to 12-hour period</li> <li>■ do not exceed 3 [insert dosage unit] 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>

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**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

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

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

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

**E**



Stop using this product and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- stomach pain occurs with use of this product.
- any new or unexpected symptoms occur.
- fever gets worse or lasts more than 3 days.
- pain gets worse or lasts more than 10 days.

As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. **IT IS ESPECIALLY IMPORTANT NOT TO USE KETOPROFEN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY 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 accidental overdose, seek professional assistance or contact a poison control center right away.

**Directions**

- do not take more than directed
- take with a full glass of water or other liquid

**Adults:**

- take 1 tablet every 4-6 hours while symptoms occur
- if pain or fever does not get better, you may take 1 more tablet, but do not take more than 2 tablets in any 4-6 hour period or more than 6 tablets in any 24 hour period

- with experience some people may find they need 2 tablets for the first dose
- the smallest effective dose should be used

**Children:** do not give to children under age 16 unless directed by a doctor.

Store at 20-25°C (68-77°F).

Avoid excessive heat (30°C/86°F).

Read all warnings and directions before use. Keep carton.

If you have any questions or comments please call 1-800-ORUDIS

**NOW...IN NON-PRESCRIPTION STRENGTH**

# ORUDIS

KETOPROFEN TABLETS 12.5 mg

## KT

Pain Reliever/Fever Reducer

100 COATED TABLETS



**NOW...IN NON-PRESCRIPTION STRENGTH**

# ORUDIS

KETOPROFEN TABLETS 12.5 mg

## KT

Pain Reliever/Fever Reducer

100 COATED TABLETS



## ORUDIS KT

THE FOIL SEAL UNDER BOTTLE CAP IMPRINTED "SEALED FOR YOUR PROTECTION" IS YOUR ASSURANCE THAT THIS PACKAGE HAS NOT BEEN OPENED

**Active Ingredients:** cellulose, D&C Yellow #10 Lake, FD&C Blue #1 Lake, iron oxide, pharmaceutical glaze, polyethylene glycol, sodium benzoate, sodium lauryl sulfate, starch, stearic acid, sugar, titanium dioxide, wax. Contains FD&C Yellow #5 Lake (tartrazine) as a color additive.

Manufactured by: Whitehall-Flacke Healthcare  
Madison, NJ 07940 By arrangement with RHOE-POLLENC France  
© Whitehall-Flacke Healthcare

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**Active Ingredient (in each tablet)**  
Ketoprofen 12.5 mg

**Purpose:**  
Pain reliever/fever reducer

**Uses:** temporarily relieves minor aches and pains due to:

- common cold
- headache
- toothache
- muscular aches
- backache
- minor pain of arthritis
- menstrual cramps

Temporarily reduces fever

**Warnings**

**Allergy alert:** ketoprofen 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 ketoprofen or other pain relievers/fever reducers. Ketoprofen may cause stomach bleeding.

**Do not use**

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- with any other pain reliever/fever reducer
- with any other product containing ketoprofen

**Ask a doctor before use if**

- the painful area is red or swollen
- you take other drugs on a regular basis
- you are under a doctor's care for any continuing medical condition
- you have had problems or side effects with any pain reliever/fever reducer

0130-40/31A



**F**

**Drug Facts**

**Active Ingredient (in each tablet)**

Ibuprofen 200 mg

**Purpose**

Pain reliever/fever reducer

**Uses**

- temporarily relieves minor aches and pains due to:
  - minor pain of arthritis
  - headache
  - backache
  - menstrual cramps
  - the common cold
  - muscular aches
  - toothache
- 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**

- problems or serious side effects from taking pain relievers or fever reducers
- stomach problems that last or come back, such as heartburn, upset stomach, or pain
- ulcers
- bleeding problems
- high blood pressure, heart or kidney disease, are taking a diuretic, or are over 65 years of age

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

- under a doctor's care for any serious condition
- taking any other product that contains ibuprofen, or any other pain reliever/fever reducer
- taking a prescription drug for anticoagulation (blood thinning)
- taking any other drug

**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

**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.

***Directions***

- **do not take more than directed**
- adults and children 12 years and over
  - 1 tablet every 4 to 6 hours while symptoms persist
  - if pain or fever does not respond to 1 tablet, 2 tablets may be used
  - do not exceed 6 tablets in 24 hours, unless directed by a doctor
  - the smallest effective dose should be used
- children under 12 years: ask a doctor

***Other information***

- **each tablet contains:** *[insert applicable ingredient(s) (such as sodium and/or calcium) and number of milligrams]*
- store at 20 - 25°C (68 - 77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- *[add tamper-evident statement here]*

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

***Questions or Comments? [list toll-free phone number or list web address. (may include the days of the week and times of the day when a person is available to respond to questions)]***

[Please note: The font size, spacing, bolding, and formatting in this label are not necessarily compliant with § 201.66.]