

FAST PAIN RELIEF - ibuprofen tablet, coated
We Care Distributor Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient(in each tablet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/Fever reducer

Uses

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

- temporarily reduces fever

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

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

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- 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. 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.

- **do not take more than directed**
- **the smallest effective dose should be used**
- adults and children 12 years and over: take 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
- children under 12 years: ask a doctor

Other information

- each tablet contains: sodium 22 mg
- read all warnings and directions before use
- Keep carton or card
- store at 20 - 25°C (68 - 77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, ferric oxide red, magnesium stearate, microcrystalline cellulose, talc, titanium dioxide

Questions or Comments

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

Principal Display Panel

NDC 70005-009-25

SEE NEW WARNINGS AND DIRECTIONS

We Care

For Good Health

COMPARE TO ACTIVE INGREDIENT IN Advil®* CAPLETS

TO OPEN PUSH IN TAB AND PULL OUT

Ibuprofen 200 mg

Pain Reliever/Fever Reducer (NSAID)

- Headache
- Toothache
- Minor Pain of Arthritis
- Fever
- Muscularache
- Menstrual Cramps

Ibuprofen

This product is not manufactured or distributed by Pfizer Healthcare, owner of the registered trademark of Advil® tablets.

25 Pouches of 2 Coated Tablets

FAST PAIN RELIEF
COMPARE TO ACTIVE INGREDIENT IN
Advil[®]
CAPLETS

Ibuprofen 200 mg
Pain Reliever/
Fever Reducer (NSAID)

- Headache
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25 Pouches of 2 Coated Tablets

Drug Facts
(in each tablet)

Active Ingredient (in each tablet)
Ibuprofen 200 mg (NSAID) **Purpose**
Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Use
Temporarily relieves minor aches and pains due to:
■ headache ■ toothache ■ backache ■ menstrual cramps
■ the common cold ■ muscular aches ■ minor pain of arthritis
Temporarily reduces fever

Warnings
Allergic alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
■ hives ■ facial swelling ■ asthma (wheezing)
■ shock ■ skin redness ■ rash ■ blisters
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
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■ 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

Do not use
If you have ever had an allergic reaction to any other pain reliever/fever reducer
■ right before or after heart surgery

Ask a doctor before use if
■ stomach bleeding warning applies to you
■ you have problems or serious side effects from taking pain relievers or fever reducers
■ you have a history of stomach problems, such as heartburn
■ you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma
■ you are taking a diuretic
■ ask a doctor or pharmacist before use if you are:
■ under a doctor's care for any serious condition
■ taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin
■ taking any other drug

When using this product
■ take with food or milk if stomach upset occurs
■ the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

FAST PAIN RELIEF
COMPARE TO ACTIVE INGREDIENT IN
Advil[®]
CAPLETS

Ibuprofen 200 mg
Pain Reliever/Fever Reducer (NSAID)

- Headache
- Minor Pain of Arthritis
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Ibuprofen

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25 Pouches of 2 Coated Tablets

Drug Facts (continued)
Stop use and ask a doctor if:
■ you experience any of the following signs of stomach bleeding:
■ black stool
■ vomit blood
■ have bloody or black stools
■ have stomach pain that does not get better
■ get 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. 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
■ the smallest effective dose should be used
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■ 1 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
■ children under 12 years: ask a doctor

Other information
■ each tablet contains sodium 22 mg
■ read all warnings and directions before use.
■ keep out of reach of children.
■ store at 20°-25° (68°-77°F)
■ avoid exposure to heat above 40°C (104°F)

Inactive ingredients
colloidal silicon dioxide, croscarmellose sodium, ferrous oxide red, magnesium stearate, microcrystalline cellulose, talc, titanium dioxide

Questions or Comments
1-888-765-WE CARE (Mon-Fri 9am-5pm EST) or www.wccare distributor.com

Manufactured For / Distributed By:
Pfizer Consumer Healthcare Inc.
Hornbridge, TN 37076
www.medicines.com

DO NOT USE IF POUCH IS BROKEN OR TORN

70005009254

FAST PAIN RELIEF

ibuprofen tablet, coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70005-009 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM) | IBUPROFEN | 200 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| TALC (UNII: 7SEV7J4RIU) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|--------------|-----|--------------|-----------|
| Color | red | Score | no wccare |
|--------------|-----|--------------|-----------|

| | | | |
|-----------------|-------|---------------------|-------|
| Shape | ROUND | Size | 10 mm |
| Flavor | | Imprint Code | G2 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70005-009-02 | 4 in 1 POUCH; Type 0: Not a Combination Product | | |
| 2 | NDC:70005-009-25 | 25 in 1 CARTON | | |
| 2 | | 2 in 1 POUCH; Type 0: Not a Combination Product | | |
| 3 | NDC:70005-009-50 | 50 in 1 CARTON | | |
| 3 | | 2 in 1 POUCH; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343 | 12/02/2015 | |

Labeler - We Care Distributor Inc. (079832998)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|------------------------|
| Granules India Limited | | 918609236 | manufacture(70005-009) |

Revised: 12/2015

We Care Distributor Inc.