

IBUPROFEN- ibuprofen tablet, coated
AAA Pharmaceutical, Inc.

RES - 1110C - 2019-1012

Drug Facts

Active ingredient (in each caplet)

Ibuprofen, USP 200 mg (NSAID ¹)

¹ nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

Allergy alert

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

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

- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.
- 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.

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**
- do not take longer than 10 days, unless directed by a doctor (see Warnings)

| | |
|---------------------------------------|---|
| adults and children 12 years and over | <ul style="list-style-type: none">• take 1 caplet every 4 to 6 hours while symptoms persist• if pain or fever does not respond to 1 caplet, 2 caplets may be used• do not exceed 6 caplets in 24 hours, unless directed by a doctor |
| children under 12 years | <ul style="list-style-type: none">• ask a doctor |

Other information

- store between 20°-25°C (68°-77°F)
- avoid excessive heat above 40°C (104°F)
- read all warnings and directions before use
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, corn starch, dextrose monohydrate, hypromellose, iron oxide red, lactose monohydrate, lecithin, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone K30, pregelatinized starch, sodium carboxymellose, sodium starch glycolate, stearic acid, talc, titanium dioxide, triacetin

Distributed by:

AAA Pharmaceutical, Inc.
681 Main Street
Lumberton, NJ 08048

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Carton

RESTORE u

NDC 57344-110-03

†COMPARE TO THE ACTIVE
INGREDIENT IN ADVIL®

Ibuprofen

Tablets, USP 200 mg

Pain Reliever, Fever Reducer

(NSAID)

100 COATED CAPLETS** (**capsule-shaped tablets)

COATING FREE AREA

INK AND COATING FREE
FOR LOT AND
EXPIRATION STAMPING

0 99581 91085 3



DO NOT USE IF IMPRINTED SEAL
UNDER CAPS IS BROKEN OR MISSING

This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor of Advil®



NDC 57344-110-03
COMPARE TO THE ACTIVE
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Ibuprofen

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(NSAID)



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Drug Facts (continued)

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Distributed by:
AAA Pharmaceutical, Inc.
681 Main Street
Lumberton, NJ 08048
MADE IN INDIA

F111003RES_PD

Drug Facts (continued)

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■ any new symptoms appear

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- ask a doctor

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Active ingredient (in each caplet) **Purpose** Ibuprofen, USP 200 mg (NSAID), pain reliever/fever reducer, nonsteroidal anti-inflammatory drug

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IBUPROFEN

ibuprofen tablet, coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:57344-110 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) | IBUPROFEN | 200 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| DEXTROSE MONOHYDRATE (UNII: LX22YL083G) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | |
| SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIACETIN (UNII: XHX3C3X673) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | brown | Score | no score |
| Shape | OVAL | Size | 15mm |
| Flavor | | Imprint Code | IBU;200 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:57344-110-01 | 1 in 1 CARTON | 07/01/2017 | |
| 1 | | 24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

| | | | | |
|------------------------------|---------------------------|--|-----------------------------|---------------------------|
| 2 | NDC:57344-110-02 | 1 in 1 CARTON | 09/01/2014 | 06/30/2015 |
| 2 | | 50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| | Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| | ANDA | ANDA079129 | 09/01/2014 | |

Labeler - AAA Pharmaceutical, Inc. (181192162)

Revised: 12/2024

AAA Pharmaceutical, Inc.