

IBUPROFEN- ibuprofen tablet, film coated
Cardinal Health 107, LLC

44-438-DSP

Active ingredient (in each white tablet)

Ibuprofen USP, 200 mg (NSAID)*
*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

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

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

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

- take more or for a longer time than directed
- take a blood thinning (anticoagulant) or steroid drug

- are age 60 or older
- have 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have had stomach ulcers or bleeding problems

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer 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 a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have 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 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

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - slurred speech
 - leg swelling
 - trouble breathing

- weakness in one part or side of body
- 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 at 20 weeks or later in 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**
- 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

- store between 20°-25°C (68°-77°F)
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- avoid excessive heat 40°C (104°F)
- use by expiration date on package

Inactive ingredients

colloidal silicon dioxide, corn starch, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, triacetin

Questions or comments?

Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

Overbagged with 10 film-coated tablets per bag, NDC 55154-0669-0

WARNING: This Unit Dose package is not child resistant and is Intended for Institutional Use Only. Keep this and all drugs out of the reach of children.

Distributed By:

Cardinal Health

Dublin, OH 43017

L3432333-11024 / L3432333-21024

| | | |
|------------|------|---------------------|
| Rev. 12/25 | M-17 | Re-order No. 301559 |
|------------|------|---------------------|

Principal Display Panel

NDC 55154-0669-0

IBUPROFEN TABLETS, USP 200mg

Pain Reliever/Fever Reducer (NSAID)

10 TABLETS



B27

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

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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.

TAMPER EVIDENT: DO NOT USE IF BLISTER IS TORN OR BROKEN
OR SHOWS ANY SIGNS OF TAMPERING

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Distributed by MAJOR® PHARMACEUTICALS
Indianapolis, IN 46268
(800) 616-2471

www.majorpharmaceuticals.com
MFGD BY LNK, Hauppauge, NY 11788

Distributed by Cardinal Health
Dublin, OH 43017

L3432333-11024

Lot: Exp:

Distributed by Cardinal Health
Dublin, OH 43017
L3432333-21024

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heart problems or stroke - chest pain - slurred speech - leg
swelling - trouble breathing - weakness in one part or side of
body - 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

IBUPROFEN

ibuprofen tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|-------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55154-0669(NDC:0904-7914) |
| 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) | |
| STARCH, CORN (UNII: O8232NY3S) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |

| |
|---|
| ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK) |
| MAGNESIUM STEARATE (UNII: 70097M6I30) |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) |
| POLYDEXTROSE (UNII: VH2XOU12IE) |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) |
| STEARIC ACID (UNII: 4ELV7Z65AP) |
| TRIACETIN (UNII: XHX3C3X673) |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | WHITE | Score | no score |
| Shape | ROUND | Size | 10mm |
| Flavor | | Imprint Code | 44;438 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:55154-0669-0 | 10 in 1 BAG | 06/03/2011 | |
| 1 | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA075139 | 06/03/2011 | |

Labeler - Cardinal Health 107, LLC (118546603)