

IBUPROFEN - ibuprofen tablet, film coated
Geri-Care Pharmaceutical Corp

Active ingredient (in each brown tablet)

Ibuprofen USP, 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:

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

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

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 use 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: 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 take more than 6 tablets in 24 hours unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- store at controlled room temperature
- avoid excessive heat 40°C (104°F)

Inactive ingredients

carnauba wax, cellulose, corn starch, fumed silica gel, hypromellose, lactose, magnesium stearate, polydextrose, PEG, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide.

Questions or comments?

Call 1-800-540-3765

Package label

GERICARE

NDC 57896-941-01

SEE NEW WARNINGS

IBUPROFEN

pain reliever/fever reducer (NSAID)

COMPARE TO THE ACTIVE INGREDIENT IN ADVIL*

100 Tablets

200 mg each

Tamper Evident: Do not use if imprinted seal under cap is missing or broken.

GERICARE
NDC 57896-941-01
IBUPROFEN
PAIN RELIEVER / FEVER REDUCER
(NSAID)
COMPARE TO THE ACTIVE INGREDIENT IN ADVIL®*
100 Tablets
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Drug Facts
Active ingredient (in each brown tablet) Purpose
Ibuprofen USP 200 mg (NSAID)* Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

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:
■ shock ■ facial swelling ■ asthma (wheezing)
■ skin redness/itching ■ hives ■ 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

*This product is not manufactured or distributed by the owner of the registered trademark Advil®
Distributed By: GERI-CARE PHARMACEUTICALS CORP.
1650 63rd Street, Brooklyn, NY 11204
REV 0113

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PEEL HERE FOR MORE DRUG FACTS

Drug Facts (continued)
■ 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 □ have bloody or black stools □ vomit blood □ have stomach pain that does not get better ■ pain gets worse lasts for more than 10 days ■ fever gets worse or lasts for 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.

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Inactive ingredients: carnauba wax, cellulose, corn starch, fumed silica gel, hypromellose, lactose, magnesium stearate, polydextrose, PEG, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide.

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STOP PEELING

IBUPROFEN

ibuprofen tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:57896-941 |
| 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 |
|--|----------|
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| LACTOSE (UNII: J2B2A4N98G) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYDEXTROSE (UNII: VH2XOU12IE) | |
| POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | brown | Score | no score |
| Shape | ROUND | Size | 10 mm |
| Flavor | | Imprint Code | 44291 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:57896-941-01 | 100 in 1 BOTTLE | | |
| 2 | NDC:57896-941-10 | 1000 in 1 BOTTLE | | |
| 3 | NDC:57896-941-05 | 50 in 1 BOTTLE | | |
| 4 | NDC:57896-941-25 | 250 in 1 BOTTLE | | |
| 5 | NDC:57896-941-50 | 500 in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA075010 | 01/01/2004 | |

Labeler - Geri-Care Pharmaceutical Corp (611196254)

Registrant - Geri-Care Pharmaceutical Corp (611196254)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------|---------|-----------|---------------------|
| Geri-Care Pharmaceutical Corp | | 611196254 | repack(57896-941) |

Revised: 1/2013

Geri-Care Pharmaceutical Corp