

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

GC 941

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
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

- 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

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
- you have symptoms of heart problems or stroke:
 - chest pain - trouble breathing - leg swelling
 - slurred speech - weakness in one part or side of body
- 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 (1-800-222-1222) right away.

Directions

- **do not use 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 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

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.

GERI CARE
NDC 57896-941-01

IBUPROFEN

PAIN RELIEVER / FEVER REDUCER
(NSAID)

COMPARE TO THE ACTIVE INGREDIENT IN ADVIL®*

PACKAGE NOT CHILD RESISTANT

**100 Tablets
200 mg Each**

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

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 muscular aches toothache
 backache menstrual cramps 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:

■ shock ■ facial swelling ■ asthma (wheezing) ■ rash
 ■ skin redness ■ hives ■ 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 ■ take more or for a longer time than directed ■ have had stomach ulcers or bleeding problems

■ take a blood thinning (anticoagulant) or steroid drug (aspirin, ibuprofen, naproxen, or others)
 ■ have 3 or more alcoholic drinks every day while using this product

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

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

*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

3 57896 94101 7

PEEL HERE FOR MORE DRUG FACTS

STOP PEELING

Questions or comments? Call 1-800-540-3765

Other information ■ store between 20°-25°C (68°-77°F) ■ avoid excessive heat 40°C (104°F)

Inactive ingredients: canauba wax, colloidal silicon dioxide, cellulose, corn starch, hypromellose, lactose, magnesium stearate, polydextrose, PEG, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide.

■ children under 12 years: ask a doctor

■ 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 Poison Control Center (1-800-222-1222) right away.

Directions ■ do not use 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 take more than 6 tablets in 24 hours unless directed by a doctor

■ children under 12 years: ask a doctor

■ 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 Poison Control Center (1-800-222-1222) right away.

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: have bloody or black stools vomit blood

■ feel faint have stomach pain that does not get better

■ you have symptoms of heart problems or stroke: chest pain trouble breathing leg swelling

■ slurred speech weakness in one part or side of body

■ pain gets worse or 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

Drug Facts (continued)

■ 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

Ask a doctor or pharmacist be fore 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

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: WK2XYH10QM) (IBUPROFEN - UNII:WK2XYH10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (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	10mm
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; Type 0: Not a Combination Product	09/01/2017	
2	NDC:57896-941-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2017	
3	NDC:57896-941-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2017	
4	NDC:57896-941-25	250 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2017	
5	NDC:57896-941-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2017	
6	NDC:57896-941-20	1 in 1 CARTON	02/01/2012	
6		200 in 1 BOTTLE; Type 0: Not a Combination Product		

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)