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

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

## Inactive ingredients

carnauba wax, colloidal silicon dioxide, cellulose, corn starch, 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

# **IBUPROFEN** 200 mg

PAIN RELIEVER/ FEVER REDUCER (NSAID)



100 Tablets

 taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin ■ taking any other drug

under a doctor's care for any serious condition

When using this product

Take with food or milk if stomach upset occurs

Ask a doctor or pharmacist before use if you are

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

Stop use and ask a doctor if ■ you experience any of the following signs of stomach bleeding: a feel faint a have bloody or black stools a vomit blood

you have symptoms of heart problems or stroke

□ have stomach pain that does not get better

# Active ingredient (in each brown tablet) Orua Facts

..... Pain reliever/fever reduce Uses 

temporarily relieves minor aches and pains due to: atory drug 30 mg (NSAID)\* buprofen USF

a the common cold temporarily reduces fever □ toothache menstrual cramps muscular aches minor pain of arthritis headache backache

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

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

redness or swelling is present in the painful area

any new symptoms appear

■ pain gets worse or lasts for more than 10 days ■ fever gets worse or lasts for more than 3 days

weakness in one part or side of body

a chest pain a trouble breathing a leg swelling a slurred speech

■ shock ■ facial swelling ■ asthma (wheezing) ■ skin reddening ■hives ■ rash ■ blisters If an allergic reaction occurs, stop use

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you.

It take more or for a longer time than directed and seek medical help right away.

*Directions* ■ do not take more than directed

1-800-222-1222) right away.

the smallest effective dose should be used

adults and children 12 years and over:

■ have 3 or more alcoholic drinks every day while using this product ■ 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

children under 12 years: ask a doctor hours unless directed by a doctor

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

Ask a doctor before use if stomach bleeding warning

pain reliever/fever reducer

applies to you ■ you have problems or serious side effects from taking pain relievers or fever reducers

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1295 Towbin Ave, Lakewood, NJ 0870

Do not use ■right before or after heart surgery ■ if you have ever had an allergic reaction to any other

longer than directed

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

magnesium stearate, polydextrose, PEG, red iron oxide sodium starch glycolate, stearic acid, titanium dioxide. colloidal silicon dioxide, corn starch, hypromellose, lact *lnactive ingredients:* carnauba wax, cellulose

STOP PEELING

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

**REV 1122** 

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# **IBUPROFEN**

you have high blood pressure, heart disease, liver cirrhosis

kidney disease, asthma, or had a stroke

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
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				

P	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	09/01/2022	
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 I	nformation		
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)