# IBU TABS- ibuprofen tablet, film coated Rapid Care, Inc.

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### RapidCare - Ibuprofen Tablets, USP 200mg

#### Active Ingredient (in each tablet)

Ibuprofen USP, 200mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

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

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

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

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chances are 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.

- 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
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart
- disease, liver cirrhosis, kidney disease, asthma, or stroke
- 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
- weakness in one part or side of body
- slurred speech
- leg swelling
- 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

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. 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:

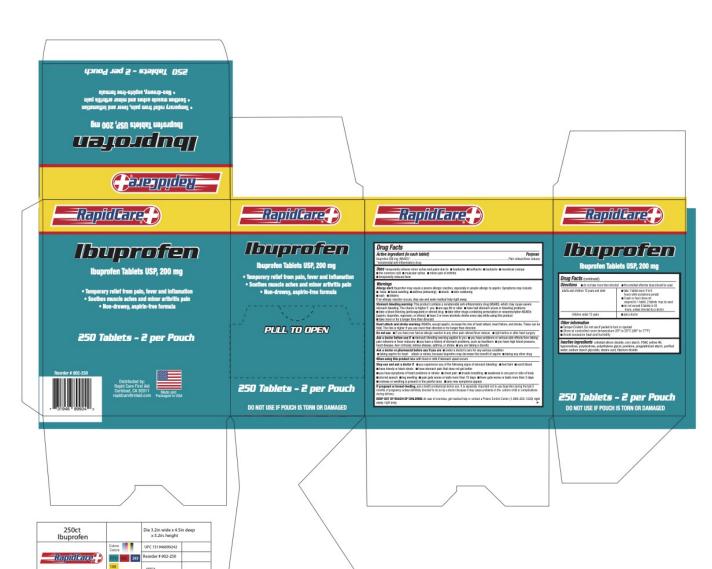
ask a doctor

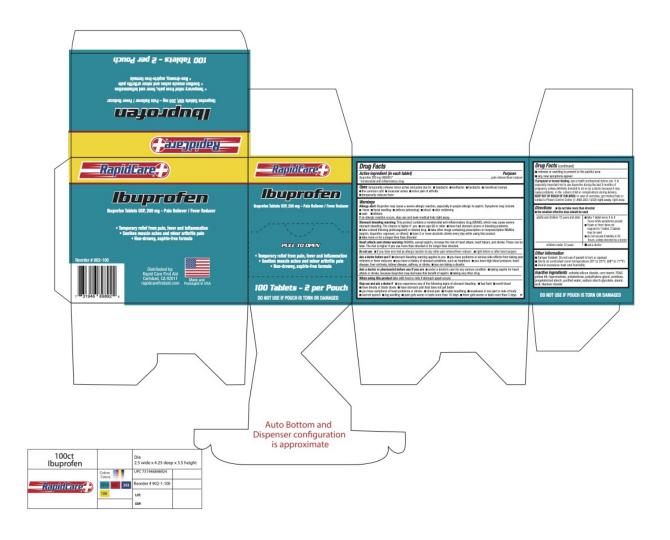
#### Other information

- Tamper Evident. Do not use if packet is torn or opened
- Store at controlled room temperature 20° to 25°C (68° to 77°F)
- Avoid excessive heat and humidity

colloidal silicon dioxide, corn starch, FD&C yellow #6, hypromellose, polydextrose, polyethylene glycol, povidone,

pregelatinized starch, purified water, sodium starch glycolate, stearic acid, titanium dioxide





#### **IBU TABS**

ibuprofen tablet, film coated

#### **Product Information**

**Product Type HUMAN OTC DRUG Item Code (Source)** NDC:73659-012

**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) POLYDEXTROSE (UNII: VH2XOU12IE) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3MJQ0SDW1A)

POVIDONE (UNII: FZ989GH94E)

| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                      |  |
|--|--|
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) |  |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8)                     |  |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)             |  |
| WATER (UNII: 059QF0KO0R)                                 |  |
| STEARIC ACID (UNII: 4ELV7Z65AP)                          |  |
| STARCH, CORN (UNII: O8232NY3SJ)                          |  |

| Product Characteristics |                   |              |                          |  |  |  |
|-------------------------|-------------------|--------------|--------------------------|--|--|--|
| Color                   | red (film coated) | Score        | score with uneven pieces |  |  |  |
| Shape                   | ROUND             | Size         | 10mm                     |  |  |  |
| Flavor                  |                   | Imprint Code |                          |  |  |  |
| Contains                |                   |              |                          |  |  |  |

| P | Packaging            |   |                         |                       |  |  |  |
|---|----------------------|---|-------------------------|-----------------------|--|--|--|
| # | Item Code            | Package Description                             | Marketing Start<br>Date | Marketing End<br>Date |  |  |  |
| 1 | NDC:73659-012-<br>01 | 50 in 1 BOX                                     | 04/15/2022              |                       |  |  |  |
| 1 |                      | 2 in 1 POUCH; Type 0: Not a Combination Product |                         |                       |  |  |  |
| 2 | NDC:73659-012-<br>02 | 125 in 1 BOX                                    | 04/15/2022              |                       |  |  |  |
| 2 |                      | 2 in 1 POUCH; Type 0: Not a Combination Product |                         |                       |  |  |  |

| Marketing Information |   |                         |                       |  |  |
|-----------------------|---|-------------------------|-----------------------|--|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |  |
| ANDA                  | ANDA079174                                  | 04/15/2022              |                       |  |  |
|                       |   |                         |                       |  |  |

# Labeler - Rapid Care, Inc. (877432778)

Revised: 4/2022 Rapid Care, Inc.