

**EASY CARE FIRST AID IBUPROFEN- ibuprofen tablet, coated**  
**Tender Corporation**

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**Easy Care First Aid Ibuprofen**

***Drug Facts***

***Active ingredient***

Ibuprofen 200 mg (NSAID)

\*nonsteroidal antiinflammatory drug

***Purpose***

Pain reliever/fever reducer

***Uses***

**Temporarily relieves minor aches and pains associated with**

- headache ■ toothache ■ backache ■ menstrual cramps
- common cold ■ muscular aches ■ minor arthritis pain

**Temporarily reduces fever**

***Warnings***

**Allergy alert:**

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

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

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

**Stomach bleeding warning:**

**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 or 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**

- you have problems or serious side effects from taking pain relievers or fever reducers
- 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

### **Ask a doctor or pharmacist before use if you are**

- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any serious condition
- 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 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
- 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 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 or unexpected 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 specifically 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 older)**

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 :**

Do not give to children under 12 years of age.

### ***Other information***

- read all product information before using
- store at 68-77°F (20-25°C)
- avoid excessive heat 40°C (above 104°F)
- tamper evident sealed packets
- do not use any opened or torn packets

### ***Inactive ingredients***

carnauba wax\*, corn starch, hypromellose\*, iron oxide red, lactose\*, magnesium stearate\*, microcrystalline cellulose\*, polydextrose\*, polyethylene glycol, polyvinyl alcohol\*, povidone K30\*, silicon dioxide, sodium starch glycolate, stearic acid, talc\*, titanium dioxide

*\*may contain*

### **Easy Care First Aid Ibuprofen**

2 Tablets

See Card for Complete Product Information

EASY CARE  
first aid™

# Ibuprofen

2 Tablets

**Active ingredient (in each tablet)** Purpose  
Ibuprofen (NSAID\*) 200mg... Pain reliever/fever reducer  
\*nonsteroidal anti-inflammatory drug

## Uses

Temporarily relieves minor aches and pains associated with

- headache
- toothache
- backache
- menstrual cramps
- common cold
- muscular aches
- minor arthritis pain

Temporarily reduces fever.

## Warnings

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

Symptoms may include:

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

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

Store at 68-77°F (20-25°C) • Avoid excessive heat, above 104°F (40°C) • Tamper-evident sealed packets

• Do not use any opened or torn packets  
Mfd. for Tender Corp • Littleton, NH 03561

## Warnings (continued)

**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 thinner (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 or 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.

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**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)

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SEE CARD FOR COMPLETE PRODUCT INFORMATION  
item# 5010-0181

## EASY CARE FIRST AID IBUPROFEN

ibuprofen tablet, coated

### Product Information

|                         |                |                    |                |
|-------------------------|----------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:44224-0018 |
| 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)     |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)     |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)  |          |
| POVIDONE K30 (UNII: U725QWY32X)     |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675) |          |

|   |  |
|---|--|
| <b>SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)</b> |  |
| <b>POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)</b>        |  |
| <b>TALC (UNII: 7SEV7J4R1U)</b>                                  |  |
| <b>POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)</b>      |  |

### Product Characteristics

|                 |                     |                     |          |
|-----------------|---------------------|---------------------|----------|
| <b>Color</b>    | red (Reddish Brown) | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND               | <b>Size</b>         | 10mm     |
| <b>Flavor</b>   |                     | <b>Imprint Code</b> | G;2      |
| <b>Contains</b> |                     |                     |          |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:44224-0018-2 | 50 in 1 BOX                                      | 01/26/2017           |                    |
| 1 |                  | 2 in 1 PACKET; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:44224-0018-1 | 2 in 1 PACKET; Type 0: Not a Combination Product | 10/01/2019           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA079174                               | 01/26/2017           |                    |

**Labeler** - Tender Corporation (064437304)

Revised: 10/2019

Tender Corporation