

# **IBUPROFEN- ibuprofen tablet, coated**

## **Family Dollar (FAMILY WELLNESS)**

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### **Drug Facts**

#### **Active ingredient (in each 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
  - muscular aches
  - toothache
  - minor pain of arthritis
  - backache
  - the common cold
  - menstrual cramps
- temporarily reduces fever

#### **Warnings**

**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 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**

- you have problems or serious side effects from taking pain relievers or fever reducers
- the 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, or 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
  - have bloody or black stools
  - vomit blood
  - have stomach pain that does not get better
- you have symptoms of heart problem or stroke:
  - chest pain
  - slurred speech
  - leg swellin
  - trouble breathing
  - weakness in one part or side of body
- 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 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. (1-800-222-1222)

**Directions**

- **do not take more than directed**
- **the smallest effective dose should be used**
- 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: ask a doctor

**Other information**

- store between 20°-25°C (68°-77°F). Avoid excessive heat above 40°C (104°F).

**Inactive ingredients**

colloidal silicon dioxide, corn starch, iron oxide red, macrogol/PEG, polyvinyl alcohol-part hydralyzed, povidone (k-30), sodium starch glycolate, stearic acid, talc, titanium dioxide,

**Questions or comments?**

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

**Principal Display Panel**

COMPARE TO THE ACTIVE INGREDIENT OF ADVIL®†

**Ibuprofen**

Tablets USP, 200 mg

Pain Reliever/Fever Reducer **(NSAID)**

COATED TABLETS

Gluten free

†This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor of Advil®.

**TAMPER-EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

**DISTRIBUTED BY: MIDWOOD BRANDS, LLC**

10611 MONROE RD., MATTHEWS, NC 28105

Product Label

COMPARE TO THE ACTIVE  
INGREDIENT IN ADVIL®

NDC 55319-568-52

**Ibuprofen**  
Tablets USP, 200 mg  
Pain Reliever/  
Fever Reducer  
(NSAID)

Gluten free

250 COATED TABLETS

FAMILY  
wellness™

**Drug Facts**

**Active ingredient (in each 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  
■ muscular aches  
■ minor pain of arthritis  
■ backache  
■ the common cold  
■ menstrual cramps  
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**Warnings**  
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■ hives  
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■ 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 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.

**Drug Facts (continued under label)**

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10611 MONROE RD., MATTHEWS, NC 28105

**NOT 100% SATISFIED?** Return package and unused product within 30 days to any Family Dollar store for a refund (with receipt) or exchange.

SKU# 0913029

PLD-A446C LB006131

Exp. Date:

Lot No.:

**PEEL HERE**

**Drug Facts (continued)**

**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 ■ the 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

**Stop use and ask a doctor if** ■ you experience any of the following signs of stomach bleeding: ■ have bloody or black stools ■ feel faint ■ vomit blood ■ have stomach pain that does not get better ■ you have symptoms of heart problems or stroke: ■ chest pain ■ slurred speech ■ leg swelling ■ trouble breathing ■ weakness in one part or side of body ■ 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

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**Directions** ■ **do not take more than directed** ■ **the smallest effective dose should be used** ■ 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: ask a doctor

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

**Inactive ingredients** colloidal silicon dioxide, corn starch, iron oxide red, magnesium/PEG, polyvinyl alcohol-part, hydroxyzed, povidone K30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

**Questions or comments?** Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

FAMILY WELLNESS Ibuprofen Tablets

IBUPROFEN

ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-568
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
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	

Product Characteristics			
<b>Color</b>	brown	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	G2
<b>Contains</b>			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-568-25	1 in 1 BOX	06/30/2017	04/26/2024
1		250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:55319-568-10	1 in 1 BOX	06/30/2017	04/26/2024
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:55319-568-50	1 in 1 BOX	06/30/2017	04/26/2024
3		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:55319-568-52	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2017	04/26/2024

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	06/30/2017	04/26/2024

**Labeler** - Family Dollar (FAMILY WELLNESS) (024472631)