# IBUPROFEN- ibuprofen tablet, coated Family Dollar (FAMILY WELLNESS)

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# **Drug Facts**

# Active ingredient (in each Brown tablet)

Ibuprofen 200 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

# **Purpose**

Pain reliever/fever reducer

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Pain reliever/fever reducer

### Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - minor pain of arthritis
  - toothache
  - 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 an 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
- 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:
  - o 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 the 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 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 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 at 20°-25°C (68°-77°F)

# Inactive ingredients

colloidal silicon dioxide, corn starch, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, iron oxide red, sodium starch glycolate, talc, titanium dioxide, triacetin

# Questions or comments?

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

# **Principal Display Panel**

COMPARE TO THE ACTIVE INGREDIENT IN ADVIL® CAPLETS†

**IBUPROFEN** 

Tablets USP, 200 mg

Pain Reliever/Fever Reducer (NSAID)\*

Gluten free

COATED CAPLETS\*\*

(\*\*Capsule-Shaped Tablets)

TAMPER-EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL

UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

†This product is not manufactured or distributed by Haleon Group of Companies, distributor of Advil® Caplets.

**DISTRIBUTED BY:** 

MIDWOOD BRANDS, LLC 500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

## **Product Label**

Exp. Date Lot No.:







# DISTRIBUTED BY: MIDWOOD BRANDS, LLC 500 VOLVO PKWY, CHESAPEAKE, VA 23320 USA

# Ask a doctor before use if

Orug Facts (continued)

- you have problems or serious side effects from taking pain relievers or fever reducers
  - stomach bleeding warning applies to you

Pain reliever/fever reducer

monsteroidal anti-inflammatory drug

'in each Brown caplet\*\*)

buprofen 200 mg

FAMILY Wellness

NSAD!

Active ingredient

**Drug Facts** 

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  - 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

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asthma (wheezing)

 facial swelling skin reddening

rashblisters

- 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

take other drugs containing prescription or nonprescription NSAIDs

(aspirin, ibuprofen, naproxen, or others)

take a blood thinning (anticoagulant) or steroid drug

have had stomach ulcers or bleeding problems

are age 60 or older

■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed

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reliever/fever reducer

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# store at 20°-25°C (68°-77°F) Other information

hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, red iron oxide, sodium starch glycolate, talc, Inactive ingredients colloidal silicon dioxide, com starch,

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

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TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED PRINTED SAFETY SEAL

KEEP OUTER CARTON FOR COMPLETE

# SEE NEW WARNINGS COMPARE TO THE ACTIVE INGREDIENT IN

ADVIL® CAPLETS!

Do not use

<u>IBUPROFEN</u> Tablets, 200 mg

temporarily relieves minor aches and pains due to:

 the common cold muscular aches

temporarily reduces fever

menstrual cramps

■ toothache

minor pain of arthritis

Pain Reliever/Fever Reducer (NSAID)\*

Gluten free



(\*\*Capsule-Shaped Tablets)



# **FAMILY WELLNESS Ibuprofen Caplets**

# **IBUPROFEN**

ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-137
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)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics				
Color	brown	Score	no score	
Shape	OVAL	Size	14mm	
Flavor		Imprint Code	IBU200	
Contains				

Pa	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319- 137-02	1 in 1 BOX	07/30/2023	
1		200 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55319- 137-10	1 in 1 BOX	07/30/2023	
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
י	NDC:55319-	1 in 1 DOV	רכחכוקס	

137-50	I III I DUA	07/30/2023		
3	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA079129	07/30/2023		

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

Revised: 8/2023 Family Dollar (FAMILY WELLNESS)