

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

Drug Facts

Active ingredient (in each Brown caplet)**

Ibuprofen 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
 - 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 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

- 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, or kidney disease
- you have 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
 - 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 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 of Advil® Caplets

SEE NEW WARNINGS

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

Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:55319-136(NDC:59556-858)		
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: 70097M6I3O)						
MICROCRYSTALLINE CELLULOSE (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	CAPSULE ((capsule shaped))		Size	14mm		
Flavor			Imprint Code	IBU200		
Contains						
Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:55319-136-24	1 in 1 BOX	08/31/2023			
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				
2	NDC:55319-136-05	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2023			
Marketing Information						
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA		ANDA079129	08/31/2023			

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

