

**IBUPROFEN- ibuprofen tablet, film coated**  
**Family Dollar Services Inc**

-----  
**Family Wellness 44-393**

***Active ingredient (in each orange caplet)***

Ibuprofen USP, 200 mg (NSAID)\*  
\*nonsteroidal anti-inflammatory drug

***Purpose***

Pain reliever/fever reducer

***Uses***

- temporarily relieves minor aches and pains due to:
  - headache
  - backache
  - menstrual cramps
  - toothache
  - the common cold
  - muscular aches
  - minor pain of arthritis
- temporarily reduces fever

***Warnings***

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

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

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

- take more or for a longer time than directed
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]

- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product

**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 are taking a diuretic
- you have a history of stomach problems, such as heartburn
- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke

### **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
  - weakness in one part or side of body
  - slurred speech
  - trouble breathing
  - 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.

***Directions***

- **do not take more than directed**
- **the smallest effective dose should be used**
- adults and children 12 years and over: take 1 caplet every 4 to 6 hours while symptoms persist
  - if pain or fever does not respond to 1 caplet, 2 caplets may be used
  - do not exceed 6 caplets 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 40°C (104°F)
- see end flap for expiration date and lot number

***Inactive ingredients***

carnauba wax, colloidal silicon dioxide, corn starch, FD&C yellow #6 aluminum lake, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

***Questions or comments?***

**Call 1-800-426-9391** 8:30 AM-4:00 PM ET, Monday-Friday

***Principal Display Panel***

**Family  
Wellness™**

†COMPARE TO THE  
ACTIVE INGREDIENT IN  
MOTRIN® IB CAPLETS

**IBUPROFEN**

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

ACTUAL SIZE

Film Coated Caplets\*\*

\*\*CAPSULE-SHAPED TABLETS

**100** COATED CAPLETS

NDC 55319-893-12

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

†This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark Motrin® IB Caplets. 50844 ORG122139312

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

**NOT 100% SATISFIED?**

Return within 30 days to the store of purchase for a refund (with receipt) or exchange.

No print/No varnish  
Lot & Exp date

SKU 913989

01 32251 92373 9

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

FAMILY Wellness™

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

Film Coated Caplets\*\*  
\*\*CAPSULE-SHAPED TABLETS

**100 COATED CAPLETS**

NDC 55319-893-12

ACTUAL SIZE

COMPARE TO THE ACTIVE INGREDIENT IN MOTRIN® IB CAPLETS

This product is not manufactured or distributed by Kenue Inc., owner of the registered trademark Motrin® IB Caplets. 50844 ORG122139312

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

NOT 100% SATISFIED? Return within 30 days to the store of purchase for a refund (with receipt) or exchange.

MADE IN THE USA

No Print  
Glue Area

**Drug Facts (continued)**

**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.

**Directions**

- do not take more than directed
- the smallest effective dose should be used
- adults and children 12 years and over: take 1 caplet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 caplet, 2 caplets may be used
- do not exceed 6 caplets 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 40°C (104°F)
- see end flap for expiration date and lot number

**Inactive ingredients** carnauba wax, colloidal silicon dioxide, corn starch, FD&C yellow #6 aluminum lake, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

**Questions or comments?**  
Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

B-0500-393-12-N  
ORG122139312

No Print  
Glue Area

**Drug Facts (continued)**

**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 a history of stomach problems, such as heartburn
- you are taking a diuretic
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you have problems or serious side effects from taking pain relievers or fever reducers

**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 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

No Print  
Glue Area

Family Wellness 44-393

<b>IBUPROFEN</b>			
ibuprofen tablet, film coated			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55319-893
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

### Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

Color	orange	Score	no score
Shape	OVAL	Size	14mm
Flavor		Imprint Code	44;393
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-893-12	1 in 1 CARTON	12/13/2023	
1		100 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	ANDA075139	12/13/2023	

**Labeler** - Family Dollar Services Inc (024472631)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(55319-893)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867837	manufacture(55319-893)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(55319-893)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		868734088	manufacture(55319-893)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(55319-893)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(55319-893)

Revised: 12/2023

Family Dollar Services Inc