## IBUPROFEN- ibuprofen tablet FAMILY DOLLAR

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SEE NEW WARNINGS
Ibuprofen
Tablets USP, 200 mg
Pain Reliever/Fever Reducer (NSAID)\*\*

## **Active ingredient (For Tablet)**

(in each tablet)

Ibuprofen 200 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

#### **Active ingredient (For Caplet)**

(in each 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

#### 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 ibuprofen or 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:
- 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 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 the reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

### **Directions (For Tablets)**

- 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

#### **Directions (For Caplets)**

- do not take more than directed
- the smallest effective dose should be used

Adults and children 12 years and older

- 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). [See USP Controlled Temperature]
- avoid excessive heat above 40°C (104°F)

#### **Inactive ingredients**

colloidal silicon dioxide, ferric oxide red, maize starch, polyethylene glycol, povidone k-30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide.

#### Questions or comments?

call **1-877-770-3183** weekdays 9:00 AM to 4:30PM EST.

### **Tablets & Caplets**



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Drug Facts
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(NSAD)\*\*
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Questions or comments? call 1-877-770-3188 weeksige 9:00 AM to 4:30 PM EST

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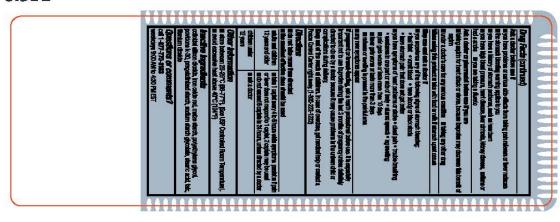
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#### SIDE 2



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Tablets USP, 200 mg Pain Reliever/Tever Reducer (NSAID)\*\*

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NOT 100%, SATISHED? Peturn package and unused product Within 90 days to eny Family Doller ators for a refund (with receipt) or exchange. Distributed By: Michwood Brancks, LLC 500 Yolvo Parkway, Chesapeales, VA 23320

The product is not manufactured or distributed by Wyath Consumer Healthcare, distributor of Adel P.

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#### Directions

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12 years and older

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a tablets. a doctor

children under 12 years mask a doctor

#### Other Information

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#### Drug Facts

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#### Drug Facts (continued)

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Questions or comments? cal 1-27-770-3163 weeking 9:00 AM to 4:30 PM EST

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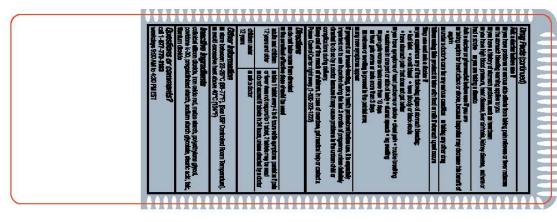
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## SIDE 2

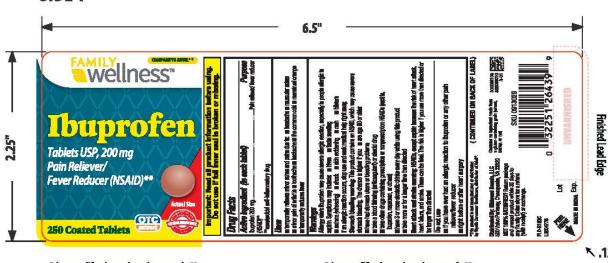


#### Dien medifications to side 2 incrming artwork:

- Updated adhesive deadener pattern
   Centered drug facts top to bottom







ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-396
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
IBUPRO FEN (UNII: WK2XYI10 QM) (IBUPRO FEN - UNII: WK2XYI10 QM)	IBUPROFEN	200 mg	

Inactive Ingredients		
Ingredient Name	Strength	
TALC (UNII: 7SEV7J4R1U)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
STARCH, CORN (UNII: O8232NY3SJ)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
PO VIDO NE (UNII: FZ989 GH9 4E)		
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)		

Product Characteristics			
Color	brown (Reddish Brown color Tablets)	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	G2
Contains			

P	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:55319-396-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	10/29/2018	
2	NDC:55319-396-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/29/2018	
3	NDC:55319-396-25	250 in 1 BOTTLE; Type 0: Not a Combination Product	10/29/2018	
4	NDC:55319-396-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2018	
5	NDC:55319-396-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	10/29/2018	

#### **IBUPROFEN**

ibuprofen tablet

Pro	duct	Info	rmation
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Route of Administration ORAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) IBUPROFEN (UNII: WK2XYI10QM)

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PO VIDO NE (UNII: FZ989 GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	brown (Reddish Brown tablets)	Score	no score
Shape	OVAL (Caplet shaped Tablets)	Size	14mm
Flavor		Imprint Code	G2
Contains			

Ш	Packaging			
Ш	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
	1 NDC:55319-397-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	10/29/2018	
Г	2 NDC:55319-397-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/29/2018	
	3 NDC:55319-397-25	250 in 1 BOTTLE; Type 0: Not a Combination Product	10/29/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	10/29/2018	

Revised: 8/2020 FAMILY DOLLAR