

**MEMBERS MARK IBUPROFEN- ibuprofen tablet, film coated**  
**Sam's West Inc**

-----  
**Sam's West, Inc. Ibuprofen Tablets, 200 mg Drug Facts**

**Active ingredient (in each tablet)**

Ibuprofen 200 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

**Purposes**

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 chances are 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 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**

- read all warnings and directions before use
- store at 20-25°C (68-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)

**Inactive ingredients**

colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, microcrystalline cellulose, polyethylene glycol, polysorbate 80, stearic acid, titanium dioxide

**Questions or comments?**

Call **1-800-809-0469** from 7:30 a.m. to 5:00 p.m. Monday-Friday EST.

**Principal Display Panel**

Compare to Advil<sup>®</sup> active ingredient

ibuprofen tablets, 200 mg

pain reliever

fever reducer

(NSAID)

actual size

600 Coated Tablets

**Compare to Advil®  
active ingredient\*\***

NDC 68196-005-61

**Member's Mark™**

ibuprofen

tablets, 200 mg  
pain reliever  
fever reducer  
(NSAID)

actual size

600  
Coated  
Tablets

**Drug Facts**

**Active ingredient (in each tablet)**      **Purposes**  
 ibuprofen 200 mg (NSAID)\*.....Pain reliever/fever reducer  
 \*nonsteroidal anti-inflammatory drug

**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 chances are 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

**Drug Facts (continued)**

**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 of 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 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**    ■ read all warnings and directions before use  
 ■ store at 20-25°C (68-77°F)  
 ■ avoid high humidity and excessive heat above 40°C (104°F)

**Inactive ingredients**    colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, microcrystalline cellulose, polyethylene glycol, polysorbate 80, stearic acid, titanium dioxide

**Questions or comments?** Call 1-800-809-0469 from 7:30 a.m. to 5:00 p.m. Monday-Friday EST.

\*\*This product is not manufactured or distributed by Pfizer, distributor of Advil®.

Not for individual resale

DISTRIBUTED BY: SANSWET, INC.  
 BETHUNVILLE, AR 72716

: A9874 ZY FS

MEMBERS MARK IBUPROFEN			
ibuprofen tablet, film coated			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68196-005
<b>Route of Administration</b>	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)			
IBUPROFEN			
200 mg			
Inactive Ingredients			
	Ingredient Name		Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
STARCH, CORN (UNII: O8232NY3SJ)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
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>	I2	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:68196-005-61	600 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2015	
2	NDC:68196-005-62	1 in 1 CARTON	08/03/2016	06/08/2018
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ANDA	ANDA072096	05/18/2015		

**Labeler** - Sam's West Inc (051957769)

Revised: 10/2020

Sam's West Inc