# IBUPROFEN- ibuprofen tablet, film coated Sam's West Inc

-----

#### Rite Aid 44-329

## Active ingredient (in each brown tablet)

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

#### Purpose

Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - the common cold
  - menstrual cramps
  - backache
  - toothache
  - 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:

- 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

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

- 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

- 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

- taking any other drug
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any serious condition

# 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

# 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 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

- use by expiration date on package
- store between 20°-25°C (68°-77°F)
- avoid excessive heat 40°C (104°F)

# Inactive ingredients

carnauba wax, colloidal silicon dioxide, corn starch, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, 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**

Compare to ADVIL® active ingredient†

NDC 68196-291-78

# Member's Mark™

#### ibuprofen

tablets USP, 200 mg

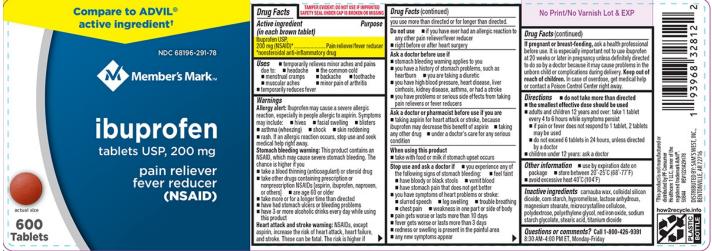
pain reliever fever reducer (NSAID)

actual size

# 600 Tablets

†This product is not manufactured or distributed by PF Consumer Healthcare 1 LLC, owner of the registered trademark Advil®. 50844 ORG122129178

#### DISTRIBUTED BY: SAM'S WEST, INC., BENTONVILLE, AR 72716



Members Mark 44-291

IBUPROFEN						
ibuprofen tablet, film coated						
Product Information						
Product Type	HUMAN OTC DRUG	ltem Code (	Source)	NDC:68	196-291	
Route of Administration	ORAL					
Active Ingredient/Active Moiety						
Ingredient Name Basis of Strength Strength						
IBUPROFEN (UNII: WK2XYI10QM) (I	BUPROFEN - UNII:WK2XYI10	QM)	IBUPROFEN		200 mg	
Inactive Ingredients						
	Ingredient Name				Strength	
CARNAUBA WAX (UNII: R12CBM0E	IZ)					
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)						
STARCH, CORN (UNII: 08232NY3S	STARCH, CORN (UNII: 08232NY3SJ)					
HYPROMELLOSE, UNSPECIFIED	(UNII: 3NXW29V3WO)					
ANHYDROUS LACTOSE (UNII: 35Y	5LH9PMK)					

MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

# Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	44;291
Contains			

# Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:68196- 291-78	600 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/1988	
2	NDC:68196- 291-14	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/1988	10/09/2015

# **Marketing Information**

	е
ANDA ANDA075010 05/24/1988	

# Labeler - Sam's West Inc (051957769)

Establishment						
Name	Ad	dress	ID/FEI	<b>Business Operations</b>		
LNK International, Inc.		0	38154464	pack(68196-291)		
Establishment						
Name	Ad	dress	ID/FEI	<b>Business Operations</b>		
LNK International, Inc.		8	32867837	manufacture(68196-291)		
Establishment						
Name	Ad	dress	ID/FEI	<b>Business Operations</b>		
LNK International, Inc.		8	32867894	manufacture(68196-291)		
Establishment						
Name	Address	ID/FEI		<b>Business Operations</b>		

LNK International, Inc.	868734088	manufacture(68196-291) , pack(68196-291)
-------------------------	-----------	--

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(68196-291)

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(68196-291)

Revised: 9/2023

Sam's West Inc