

# IBUPROFEN tablet, film coated

## Ibuprofen by

### Drug Labeling and Warnings

FDA.report (<https://fda.report/>) / Sam's West Inc (</Company/Sam-S-West-Inc>) / Ibuprofen by Drug Facts (</DailyMed/6293a134-860d-4d12-9e4b-28490f824108>)

FDA.report (<https://fda.report/>) / LNK International, Inc. (</Company/Lnk-I-N-T-Inc>) / Ibuprofen by Drug Facts (</DailyMed/6293a134-860d-4d12-9e4b-28490f824108>)

Ibuprofen by is a Otc medication manufactured, distributed, or labeled by Sam's West Inc, LNK International, Inc.. Drug facts, warnings, and ingredients follow.

Drug Details [pdf (</DailyMed/6293A134-860D-4D12-9E4B-28490F824108.pdf>)]

- **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

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- 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†



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t:

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 REV1221A29178

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**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

**Drug Facts**

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

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

**Purpose**

**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,

**Drug Facts (continued)**

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

No Print / No Varnish Area  
Lot # and Exp. Info

**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.

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■ 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

Questions or Comments? We would love to hear about your experience with this product. Call us toll-free at 1-800-426-9391 from 8:30 a.m. to 4:00 p.m. EST Mon-Fri.

This product is not manufactured or distributed by PF Consumer Healthcare 1 LLC, owner of the registered trademark Advil®. 50844 01612218178

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Members Mark 44-291

• **INGREDIENTS AND APPEARANCE**

**IBUPROFEN**

ibuprofen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC: 68196-291 (/NDC/68196-291)
Route of Administration	ORAL		

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### Inactive Ingredients

Ingredient Name	Strength
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ (/UNII/R12CBM0EIZ))	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4 (/UNII/ETJ7Z6XBU4))	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ (/UNII/O8232NY3SJ))	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO (/UNII/3NXW29V3WO))	
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK (/UNII/3SY5LH9PMK))	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30 (/UNII/70097M6I30))	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U (/UNII/OP1R32D61U))	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE (/UNII/VH2XOU12IE))	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A (/UNII/3WJQ0SDW1A))	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675 (/UNII/1K09F3G675))	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2 (/UNII/5856J3G2A2))	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP (/UNII/4ELV7Z65AP))	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP (/UNII/15FIX9V2JP))	

Flavor Imprint Code 44;291

Contains

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075010	05/24/1988	

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Labeler - Sam's West Inc (051957769)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(68196-291 (/NDC/68196-291))

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(68196-291 (/NDC/68196-291))

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(68196-291 (/NDC/68196-291))

Establishment

Name	Address	ID/FEI	Business Operations

LNK International, Inc.

967626305

pack(68196-291 (/NDC/68196-291))

Establishment

**Name**

**Address**

**ID/FEI**

**Business Operations**

LNK International, Inc.

117025878

manufacture(68196-291 (/NDC/68196-291))

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