IBUPROFEN- ibuprofen tablet, film coated
Rite Aid Corporation

Rite Aid 44-291

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:
  - muscular aches
  - headache
  - menstrual cramps
  - backache
  - the common cold
  - toothache
  - 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
- shock
- hives
- asthma (wheezing)
- skin reddening
- blisters
- 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
- have 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]

- are age 60 or older
- have had stomach ulcers or bleeding problems

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 have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you are taking a diuretic
- 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
  - 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
  - slurred speech
  - trouble breathing
  - leg swelling
  - 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

- see end flap for expiration date and lot number
- 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

TRIAL SIZE

NDC 11822-0291-2

Compare to the
active ingredient in
Advil® Tablets**

PAIN RELIEF
IBUPROFEN

IBUPROFEN TABLETS USP, 200 mg
PAIN RELIEVER/FEVER REDUCER
(NSAID)

ACTUAL SIZE

12
COATED
TABLETS

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

**This product is not manufactured or distributed by PF Consumer Healthcare 1 LLC, owner of the registered trademark Advil® Tablets.
50844 REV1221D29102

DISTRIBUTED BY: RITE AID
200 NEWBERRY COMMONS
ETTERS, PA 17319
www.riteaid.com

SATISFACTION GUARANTEE:
If you're not satisfied, we'll
happily refund your money.

TRIAL SIZE

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A7567R

B-1702-291-02-R3

REV1221D29102

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Drug Facts (continued)

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DISTRIBUTED BY: RITE AID
200 NEWBERRY COMMONS
ETTERS, PA 17319
www.riteaid.com

SATISFACTION GUARANTEE:
If you're not satisfied, we'll happily refund your money.

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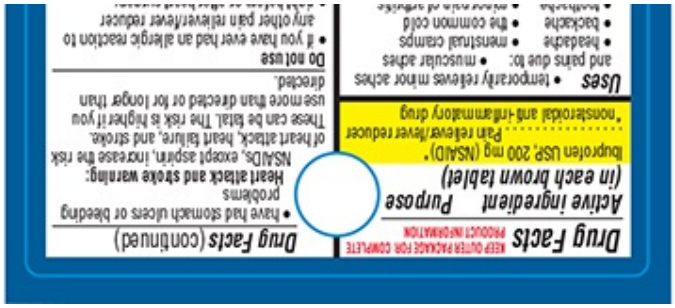

Rite Aid 44-291

IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11822-0291
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0291-2	1 in 1 CARTON	05/24/1988	
1		12 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:11822-0291-8	1 in 1 CARTON	05/24/1988	06/09/2023
2		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:11822-0291-5	1 in 1 CARTON	05/24/1988	06/09/2023
3		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:11822-0291-1	1 in 1 CARTON	05/24/1988	06/09/2023
4		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:11822-0291-3	1 in 1 CARTON	05/24/1988	06/09/2023
5		200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
6	NDC:11822-0291-9	1 in 1 CARTON	05/24/1988	06/03/2021
6		150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
7	NDC:11822-0291-4	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/1988	01/18/2021
8	NDC:11822-0291-0	1 in 1 CARTON	05/24/1988	09/04/2021
8		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
9	NDC:11822-0291-6	1 in 1 CARTON	05/24/1988	09/06/2021
9		16 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
10	NDC:11822-0291-7	1 in 1 CARTON	05/24/1988	02/06/2022
10		250 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	ANDA075010	05/24/1988	

Labeler - Rite Aid Corporation (014578892)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(11822-0291)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(11822-0291)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(11822-0291)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(11822-0291) , pack(11822-0291)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(11822-0291)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(11822-0291)