IBUPROFEN- ibuprofen tablet, film coated Lidl US LLC

Lidl 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:
 - headache
 - backache
 - toothache
 - the common cold
 - muscular aches
 - menstrual cramps
 - 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:

- skin reddening
- asthma (wheezing)
- rash
- facial swelling
- shock
- blisters
- hives

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
- are age 60 or older
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]

- 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

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- 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
 - 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
- any new symptoms appear
- redness or swelling is present in the painful area

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

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

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 the active ingredient in Advil® Tablets

NDC 71141-178-22

Actual Size

100 COATED TABLETS

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

by LiDL®

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

DISTRIBUTED BY LIDL US, LLC ARLINGTON, VA 22202 QUESTIONS? 1-844-344-5071 www.lidl.com

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



Lidl 44-291

IBUPROFEN ibuprofen tablet, film coated				
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Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71141-178	
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: 08232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
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
1	NDC:71141- 178-22	1 in 1 CARTON	05/22/2023	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:71141- 178-32	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075010	05/22/2023	

Labeler - LidI US LLC (079389709)

Establishment			
Name	Address	ID/FEI	Business Operations

LNK International, Inc.		038154464	pack(71141-178)
Establishment			
Name	Address	5 ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(71141-178)
Establishment			
Name	Address	5 ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(71141-178)
Establishment			
Name	Address I	D/FEI	Business Operations
			Business Operations (71141-178) , pack(71141-178)
Name LNK International, Inc.			•
Name			•
Name LNK International, Inc.		34088 manufacture	•
Name LNK International, Inc. Establishment	8687	34088 manufacture	e(71141-178) , pack(71141-178)
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Name LNK International, Inc. Establishment Name	8687	34088 manufacture ID/FEI	(71141-178) , pack(71141-178) Business Operations
Name LNK International, Inc. Establishment Name LNK International, Inc.	8687	34088 manufacture ID/FEI 967626305	(71141-178) , pack(71141-178) Business Operations

Revised: 4/2024

Lidl US LLC