

IBUPROFEN - ibuprofen tablet, coated
Strides Consumer LLC

Nuprin®
Ibuprofen Tablets USP, 200 mg

Important: Read all product information before using.
Keep the box for important information.

Drug Facts

Active ingredient

(in each yellow 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 chance is 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 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. (1-800-222-1222)

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**

<p>adults and children 12 years and older</p>	<ul style="list-style-type: none"> • 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
<p>children under 12 years</p>	<ul style="list-style-type: none"> • ask a doctor

Other information

- store between 20–25°C (68–77°F)
- **do not use if carton is opened. Do not use if foil inner seal imprinted with "Sealed For Your Safety" is broken or missing**

Inactive ingredients

colloidal silicon dioxide, corn starch, D&C yellow no. 10 aluminium lake, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, talc, titanium dioxide and triacetin

Questions or comments?

Call **1-855-742-7868** (toll-free)

Manufactured by:

Strides Pharma Science Ltd

605014, India.

PON/DRUGS/16 13 4193

Distributed by:

Strides Consumer LLC,

East Brunswick, NJ 08816

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www.nuprin.com

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PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Package Label (Round Shaped Tablets) - Principal Display Panel, 200 mg Tablets

See New Warnings

NDC 72927-805-02

24 Coated Tablets

Nuprin[®]

IBUPROFEN TABLETS, USP

200 mg

Pain Reliever/Fever Reducer (NSAID)*

*nonsteroidal anti-inflammatory drug

TYPE LEGEND

13 pt Helvetica Bold Oblique
7.5 pt Helvetica Bold Oblique
5 pt Helvetica Condensed Medium
7.5 pt Helvetica Bold Oblique



IBUPROFEN

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72927-805
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

STARCH, CORN (UNII: O8232NY3SJ)
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)
HYPROMELLOSES (UNII: 3NXW29V3WO)
MAGNESIUM STEARATE (UNII: 70097M6I30)
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
TRIACETIN (UNII: XHX3C3X673)

Product Characteristics

Color	YELLOW	Score	no score
Shape	ROUND (ROUND SHAPED)	Size	10mm
Flavor		Imprint Code	N
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72927-805-02	1 in 1 CARTON	09/10/2019	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:72927-805-01	1 in 1 CARTON	09/10/2019	
2		120 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207052	09/10/2019	

Labeler - Strides Consumer LLC (116975770)

Registrant - Strides Pharma Global Pte. Ltd. (659220961)

Establishment

Name	Address	ID/FEI	Business Operations
Strides Pharma Science Limited		871402375	ANALYSIS(72927-805) , MANUFACTURE(72927-805) , PACK(72927-805)