IBUPROFEN IMMEDIATE RELEASE- ibuprofen tablet, coated
Strides Pharma Inc.

Nuprin®
Ibuprofen Tablets, USP 200 mg
Drug Facts

ACTIVE INGREDIENT(S)

(in each yellow tablet or caplet**)

Ibuprofen USP 200 mg (NSAID)*****

*****nonsteroidal anti-inflammatory drug

******capsule-shaped tablets

PURPOSE

Pain reliever/fever reducer

USE(S)

- 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

- taking aspirin for heart attack or stroke, because ibuprofen USP 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 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 3days
- 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 ibuprofenduring the last 3 months of 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

adults and children 12 years and older	• take 1 tablet or caplet every 4 to 6 hours while symptoms persist • if pain or fever does not respond to 1 tablet or caplet, 2 tablets or caplets may be used • do not exceed 6 tablets or caplets 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)
- **do not use if imprinted text "SEALED for YOUR PROTECTION" on the safety seal under cap is broken or missing**
- see end panel for lot number and expiration date
- Sodium free
- Each tablet contains 0.714mg of Magnesium

INACTIVE INGREDIENT (S)

colloidal silicon dioxide, corn starch, D&C yellow no.10 aluminum 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)

MADE IN INDIA
Mfg.Lic.NO. : PON/DRUGS/16 13 4193
NUPRIN® is a registered trademark of Strides Pharma, Inc.

Manufactured for:
Strides Pharma Inc.
East Brunswick, NJ 08816
www.nuprin.com

August 2017

PRINCIPAL DISPLAY PANEL

Package Label (Round Shaped Tablets) - Principal Display Panel - 100 - Count Bottle Carton, 200 mg Tablets
See New Warnings
NDC 59556-805-06
100 Coated Tablets

***Nuprin*®**

Ibuprofen Tablets, USP 200 mg
Pain Reliever/Fever Reducer (NSAID)*
*nonsteroidal anti-inflammatory drug

Side Shown : Print Side

NVZ Non Varnish Zone

Package Label (Round Shaped Tablets) - Principal Display Panel - 100 - Count Bottle Label, 200 mg Tablets

Do not use if imprinted safety seal under cap is broken or missing

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100 Coated Tablets

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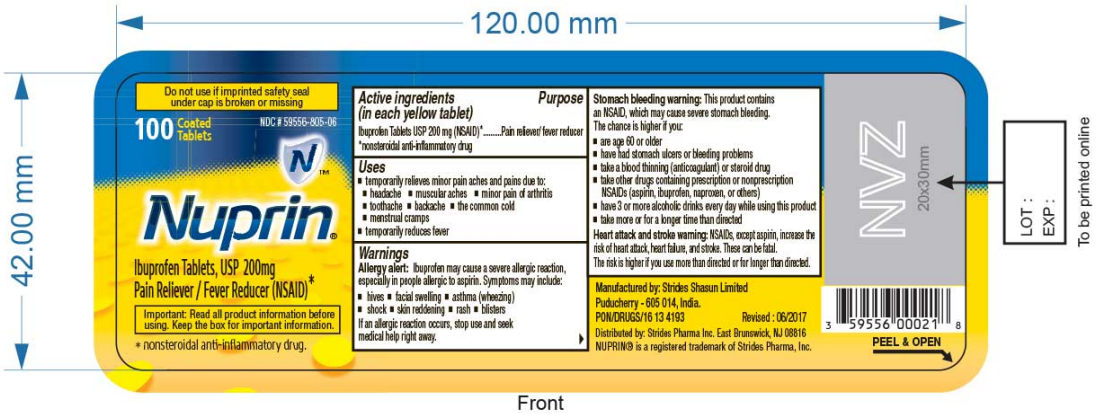
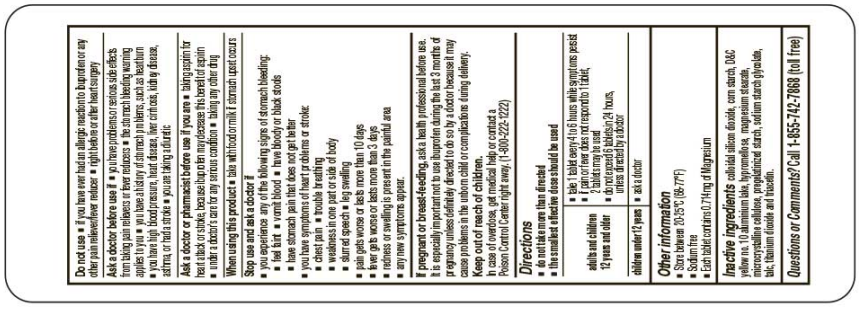
Ibuprofen Tablets, USP 200 mg
Pain Reliever/Fever Reducer (NSAID)*
Important: Read all product information before using. Keep the box for important information
*nonsteroidal anti-inflammatory drug



Front



Back

NVZ Non Varnish Zone

IBUPROFEN IMMEDIATE RELEASE

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59556-806
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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TALC (UNII: 7SEV7J4R1U)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

Color	YELLOW	**Score**	no score
Shape	CAPSULE (CAPLET SHAPED)	**Size**	14mm
Flavor		**Imprint Code**	N
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59556-806-41	1 in 1 CARTON	08/26/2016	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59556-806-06	1 in 1 CARTON	08/26/2016	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:59556-806-08	1 in 1 CARTON	08/26/2016	
3		1000 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	08/26/2016	

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ibuprofen tablet, coated

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SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TALC (UNII: 7SEV7J4R1U)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

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

Packaging

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ANDA	ANDA207052	08/26/2016	

Labeler - Strides Pharma Inc. (078868278)

Establishment

Name	Address	ID/FEI	Business Operations
Strides Shasun Limited		871402375	MANUFACTURE(59556-805, 59556-806)

Revised: 10/2017 Strides Pharma Inc.