IBUPROFEN IMMEDIATE RELEASE- ibuprofen tablet, coated
Strides Pharma Inc

Drug Facts

ACTIVE INGREDIENT(S)

(in each white 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 YOU ARE
- 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 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 during 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
- Very low sodium
- Each tablet contains 0.714 mg of Magnesium

INACTIVE INGREDIENT (S)

colloidal silicon dioxide, corn starch, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, talc, titanium dioxide and triacetin

QUESTIONS OR COMMENTS?

Call **1-855-742-7868**

Manufactured by:

Strides Shasun Limited,

Puducherry - 605 014, India

PON/DRUGS/16134193

Distributed by:

Strides Pharma Inc

East Brunswick, NJ 08816

July 2017

PRINCIPAL DISPLAY PANEL

Package Label (Round Shaped Tablets) - Principal Display Panel - 24 - Count Bottle, 200 mg Tablets

NDC 59556-811-41

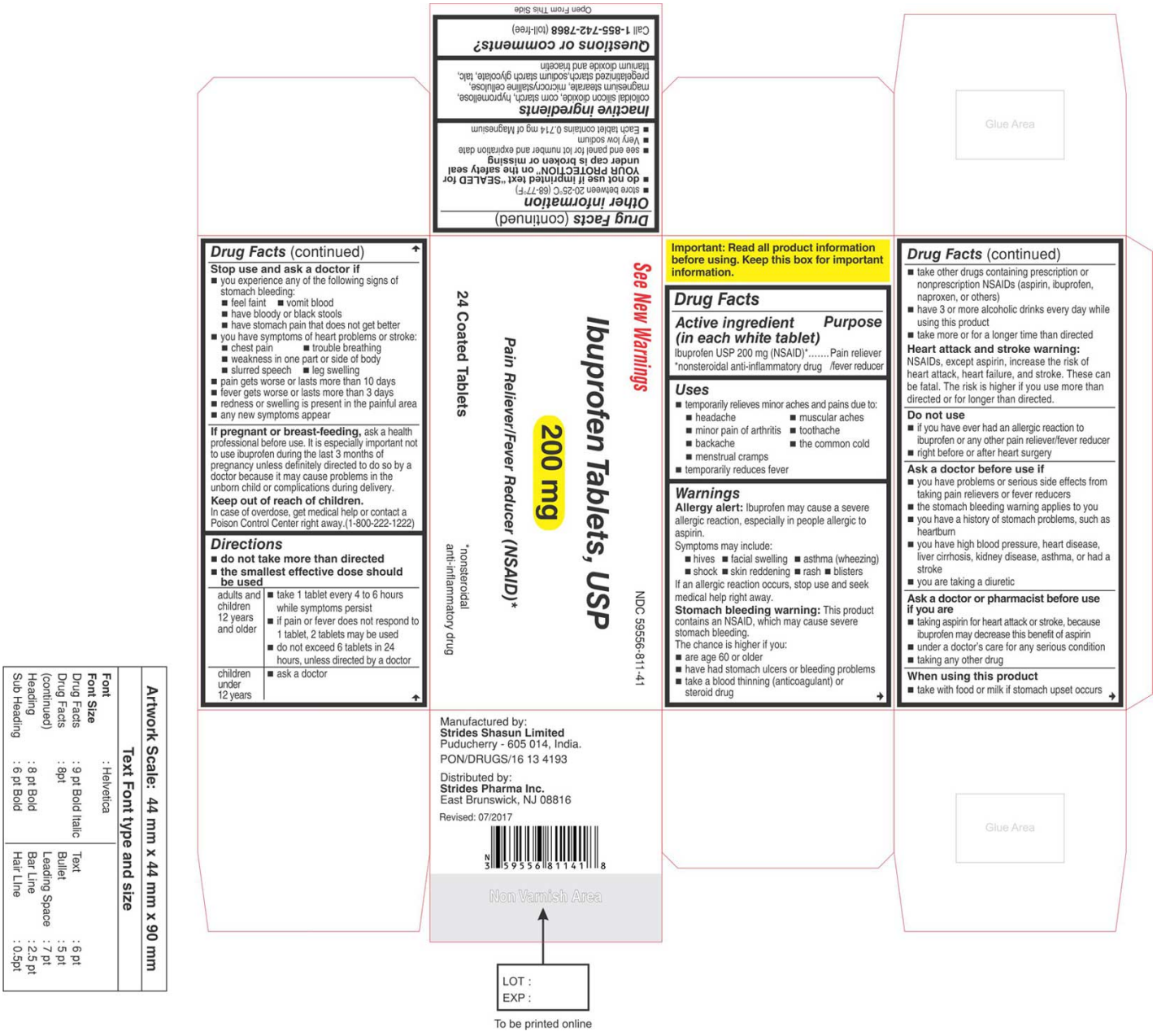
Ibuprofen Tablets USP

200 mg

Pain Reliever/Fever Reducer (NSAID)*

24 Coated Tablets

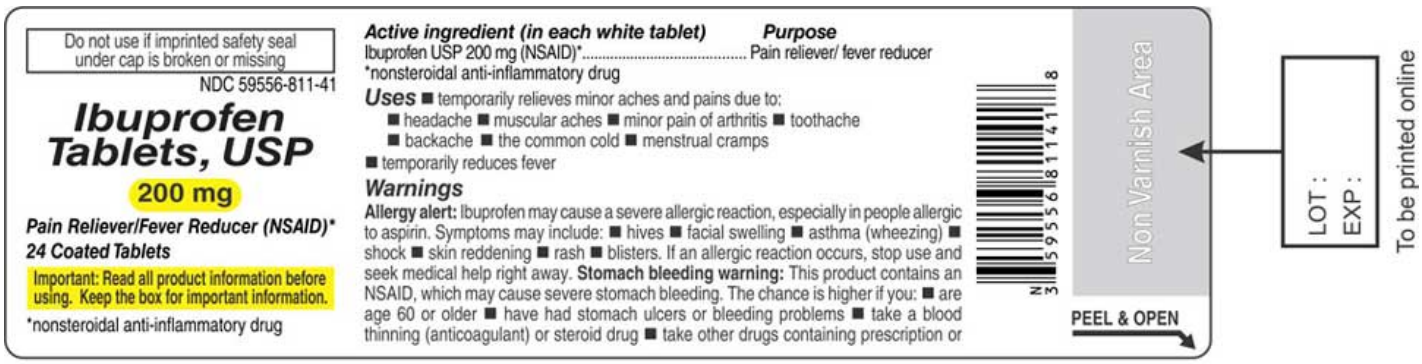
*nonsteroidal anti-inflammatory drug



Artwork Scale: 44 mm x 44 mm x 90 mm

Text Font type and size

Font	: Helvetica		
Font Size			
Drug Facts	: 9 pt Bold Italic	Text	: 6 pt
Drug Facts (continued)	: 8pt	Bullet	: 5 pt
Heading	: 8 pt Bold	Leading Space	: 7 pt
Sub Heading	: 6 pt Bold	Bar Line	: 2.5 pt
		Hair Line	: 0.5pt



Actual Artwork Scale: 32 mm x 110 mm	
Text Font type and size	
Font : Helvetica	Text : 6 pt
Font Size	Bullet : 5 pt
Heading : 8 pt Bold	Leading Space : 7 pt
Sub Heading : 6 pt Bold	

Package Label (Capsule Shaped Tablets) - Principal Display Panel - 24 - Count Bottle, 200 mg Tablets

NDC 59556-812-41

Ibuprofen Tablets USP

200 mg

Pain Reliever/Fever Reducer (NSAID)*

24 Coated Caplets**

**capsule-shaped tablets

*nonsteroidal anti-inflammatory drug

Open From This Side

Drug Facts (continued)

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
- Very low sodium
- Each tablet contains 0.714 mg of Magnesium

Inactive ingredients

colloidal silicon dioxide, corn starch, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch,sodium starch glycolate, talc, titanium dioxide and triacetin

Questions or comments?

Call **1-855-742-7866** (toll-free)

Drug Facts (continued)

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
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- pain gets worse or lasts more than 10 days
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- 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 during 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 caplet every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 caplet, 2 caplets may be used ■ do not exceed 6 caplets in 24 hours, unless directed by a doctor
children under 12 years	■ ask a doctor

See New Warnings

Ibuprofen Tablets, USP

200 mg

*Pain Reliever/Fever Reducer (NSAID)**

24 Coated Caplets**

**capsule-shaped tablets*

**nonsteroidal anti-inflammatory drug*

NDC 59556-812-41

Manufactured by:
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PON/DRUGS/16 13 4193

Distributed by:
Strides Pharma Inc.
East Brunswick, NJ 08816

Revised: 07/2017

3 59556 81241 5

Non Varnish Area

LOT :
EXP :

To be printed online

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

Drug Facts

Active ingredient (in each white caplet)	Purpose
Ibuprofen USP 200 mg (NSAID)*	Pain reliever /fever reducer

*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - minor pain of arthritis
  - toothache
  - backache
  - the common cold
  - menstrual cramps
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Drug Facts (continued)

- 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

Glue Area

Glue Area

Artwork Scale: 44 mm x 44 mm x 90 mm

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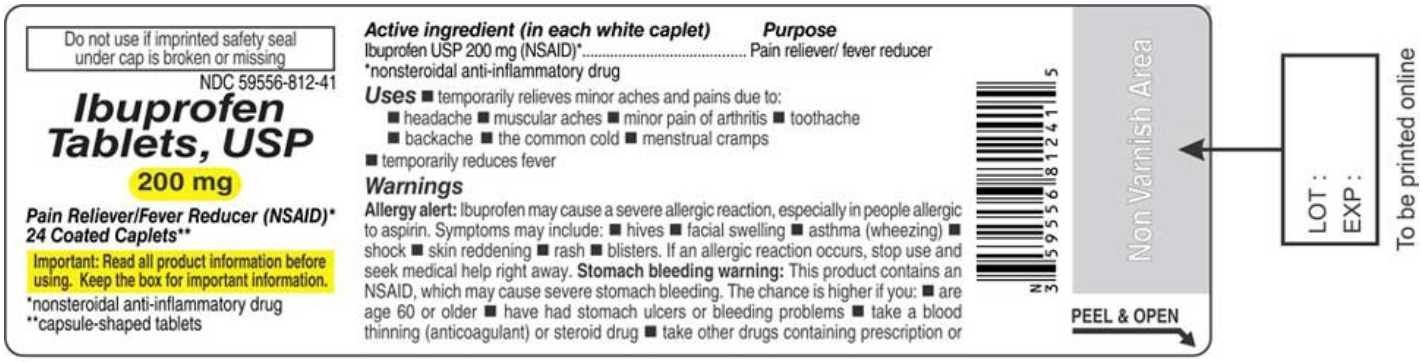

Actual Artwork Scale: 32 mm x 110 mm	
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Font : Helvetica	Text : 6 pt
Font Size	Bullet : 5 pt
Heading : 8 pt Bold	Leading Space : 7 pt
Sub Heading : 6 pt Bold	

IBUPROFEN IMMEDIATE RELEASE

ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59556-812
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)	

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)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	CAPSULE (CAPLET SHAPED)	**Size**	14mm
Flavor		**Imprint Code**	IBU200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59556-812-41	1 in 1 CARTON	06/29/2018	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59556-812-25	1 in 1 CARTON	06/29/2018	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:59556-812-06	1 in 1 CARTON	06/29/2018	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:59556-812-44	1 in 1 CARTON	06/29/2018	
4		165 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:59556-812-08	1 in 1 CARTON	06/29/2018	
5		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	ANDA206989	06/29/2018	

IBUPROFEN IMMEDIATE RELEASE

ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59556-811
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)	
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)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	ROUND (ROUND SHAPED)	**Size**	10mm
Flavor		**Imprint Code**	IBU200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59556-811-41	1 in 1 CARTON	06/29/2018	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59556-811-25	1 in 1 CARTON	06/29/2018	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:59556-811-06	1 in 1 CARTON	06/29/2018	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:59556-811-44	1 in 1 CARTON	06/29/2018	
4		165 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:59556-811-08	1 in 1 CARTON	06/29/2018	
5		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	ANDA206989	06/29/2018	

Labeler - Strides Pharma Inc (078868278)

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

Establishment

Name	Address	ID/FEI	Business Operations
Strides Pharma Science Limited		871402375	ANALYSIS(59556-811, 59556-812) , MANUFACTURE(59556-811, 59556-812) , PACK(59556-811, 59556-812)