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

Drugs Facts

ACTIVE INGREDIENT(S)

(ineach orange 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 USP 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 non prescription 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 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 ad 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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 in 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 care professional before use. it is especially important not to use ibuprofen USP 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 centre (1-800-222-1222) right away.

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
- Sodium free
- Each tablet contains 0.714 mg of Magnesium
- see end panel for lot number and expiration date.

INACTIVE INGREDIENTS (S)

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

QUESTIONS OR COMMENTS?
Call 1-855-742-7868 (toll-free): weekdays 8.00 AM to 8.00 PM EST

Manufactured by:
Strides Shasun Limited,
Puducherry - 605 014, India.
PON/DRUGS/16134193

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

May 2017

PRINCIPAL DISPLAY PANEL

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

See New Warnings

NDC 59556-856-41

Ibuprofen Tablets, USP

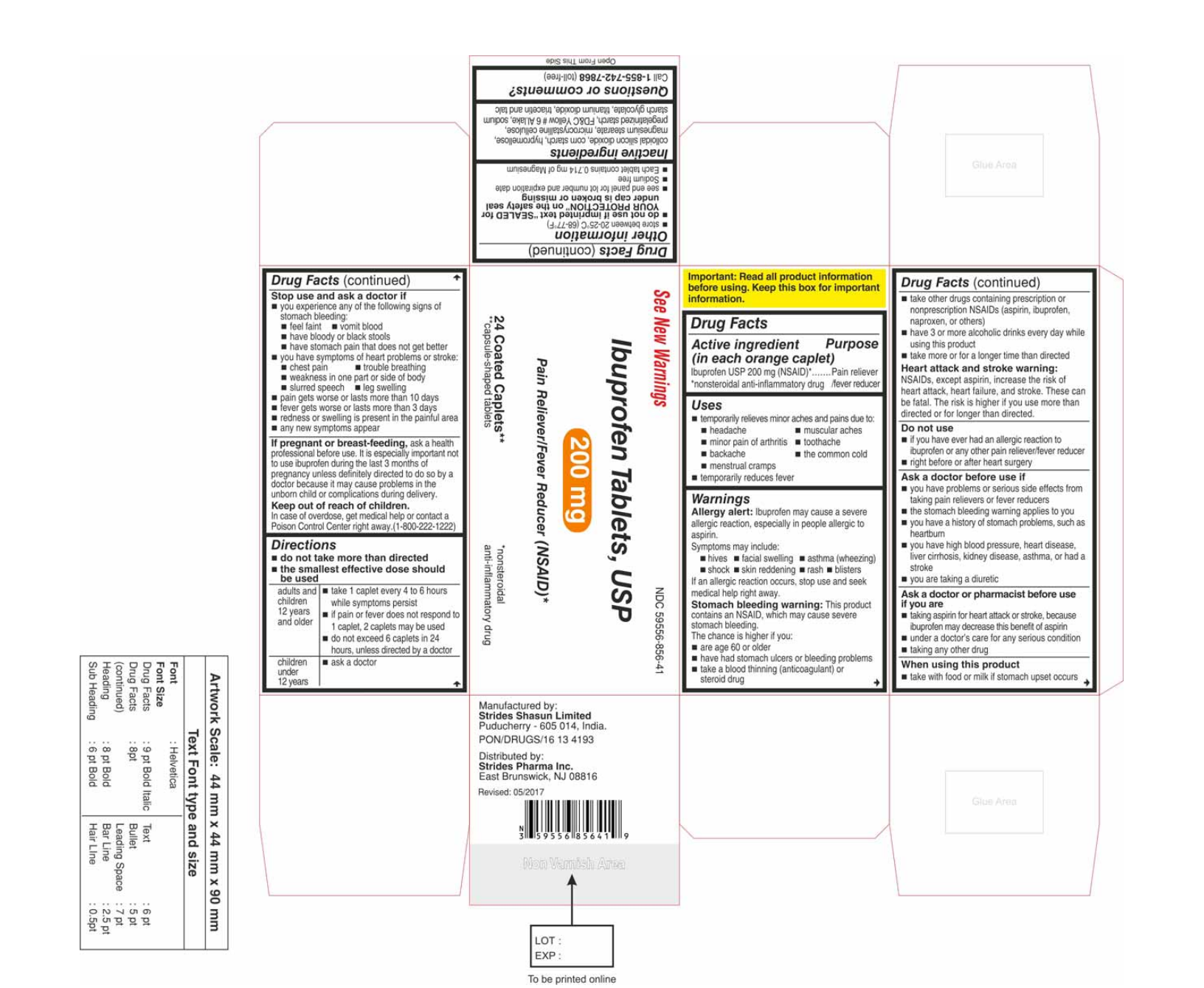
200 mg

Pain Reliever/Fever Reducer (NSAID)*

24 Coated Caplets**

**capsule-shaped tablets

*nonsteroidal anti-inflammatory drug



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Font Size			
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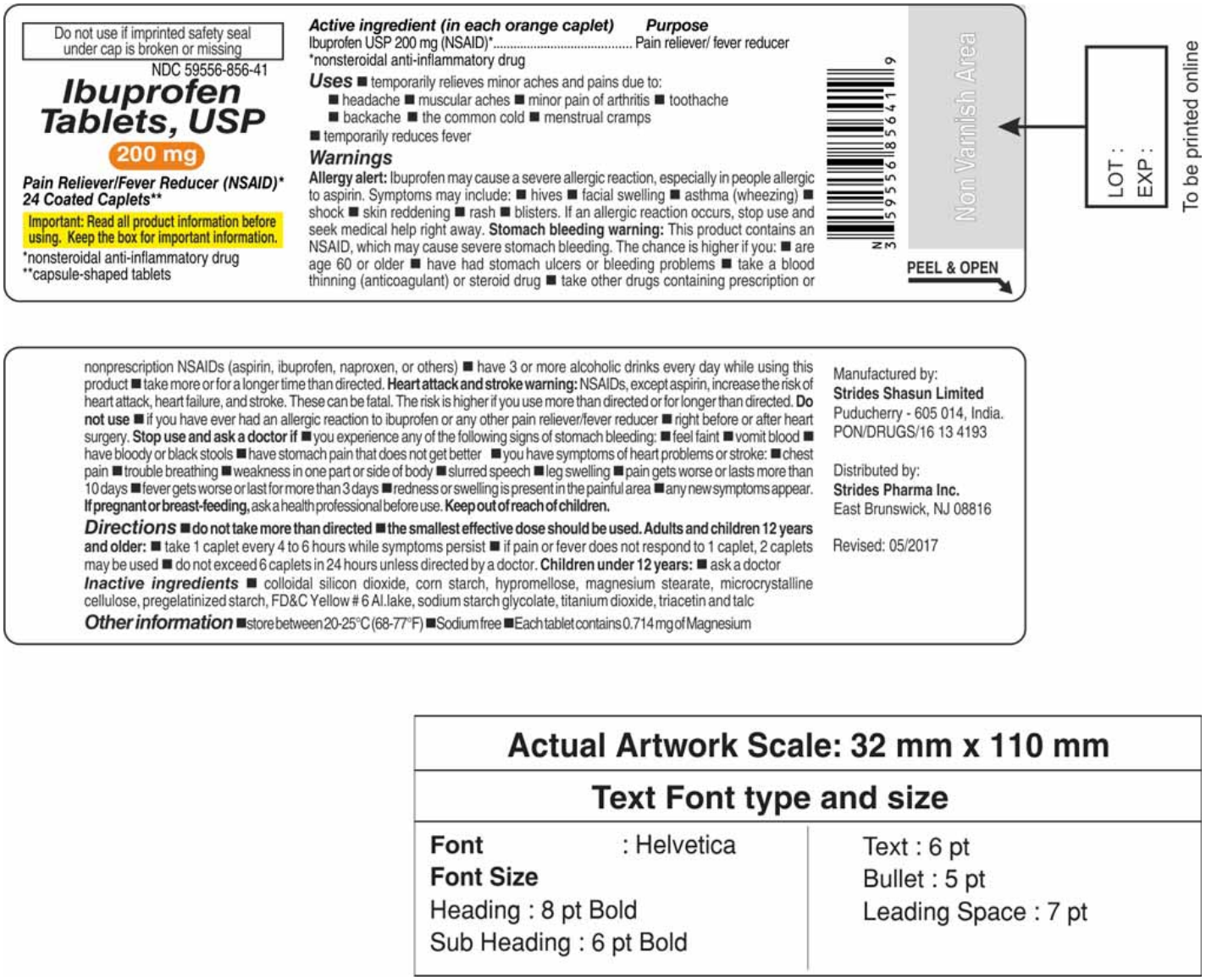
		Leading Space	: 7 pt
Heading	: 8 pt Bold	Bar Line	: 2.5 pt
Sub Heading	: 6 pt Bold	Hair Line	: 0.5pt



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

See New Warnings

NDC 59556-855-41

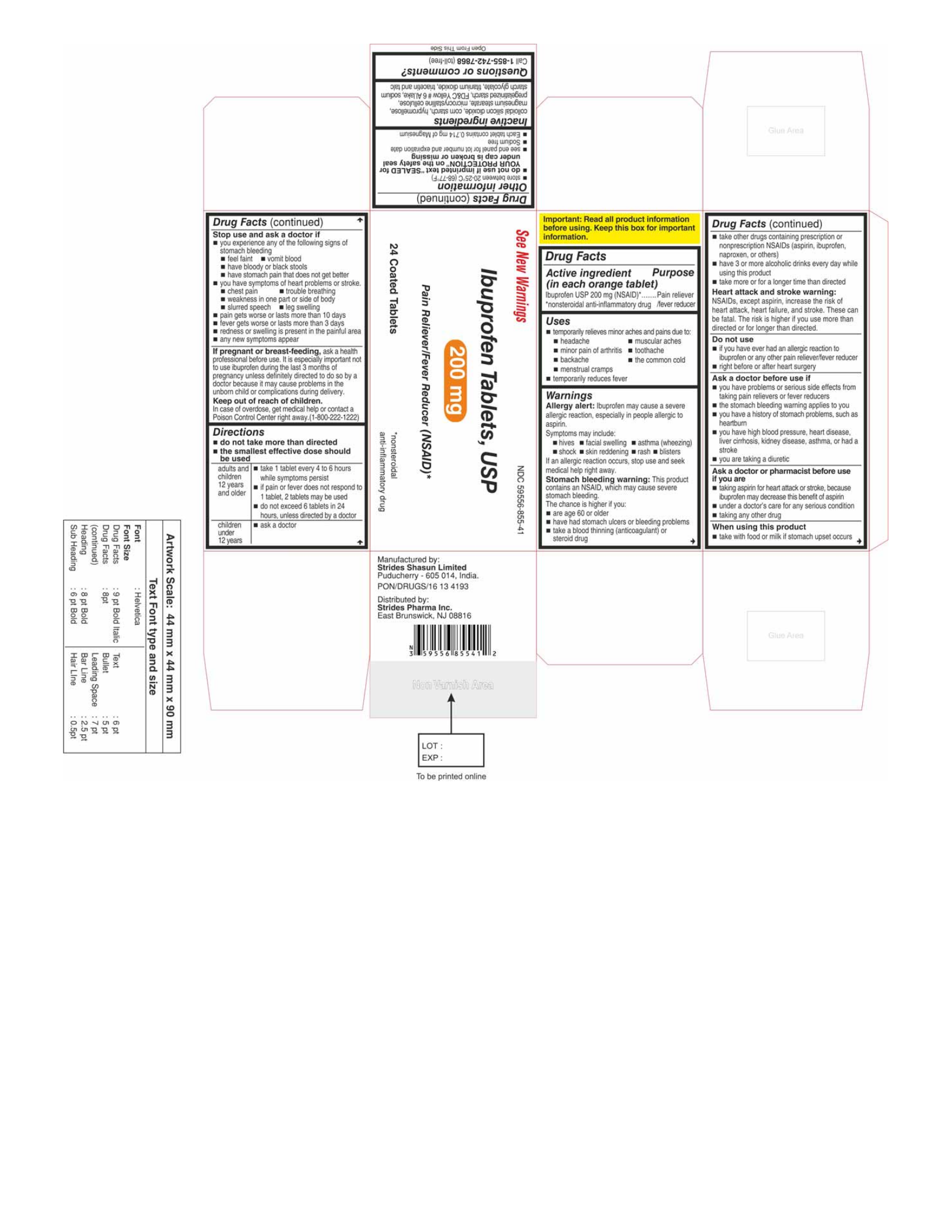
Ibuprofen Tablets, USP

200 mg

Pain Reliever/Fever Reducer (NSAID)*

24 Coated 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
■ Sodium free
■ Each tablet contains 0.714 mg of Magnesium
Inactive ingredients
colloidal silicon dioxide, corn starch, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, FD&C Yellow # 6 Al.lake, sodium starch glycolate, titanium dioxide, triacetin and talc
Questions or comments?
Call 1-855-742-7868 (toll-free)
Glue Area
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
■ 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 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
See New Warnings
Ibuprofen Tablets, USP
200 mg
Pain Reliever/Fever Reducer (NSAID)*
24 Coated Tablets
*nonsteroidal anti-inflammatory drug
NDC 59556-855-41
Manufactured by:
Strides Shasun Limited
Puducherry - 605 014, India.
PON/DRUGS/16 13 4193
Distributed by:
Strides Pharma Inc.
East Brunswick, NJ 08816
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 orange tablet) 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
■ 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
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
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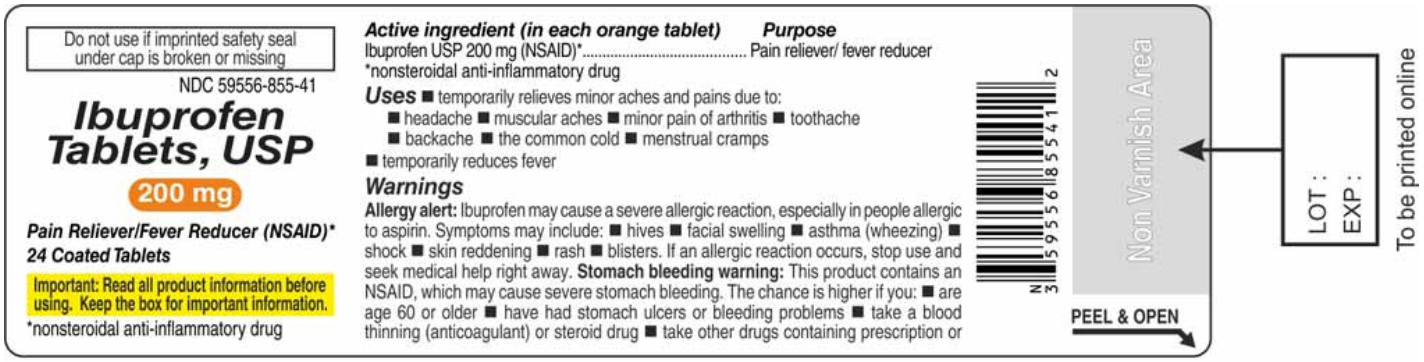

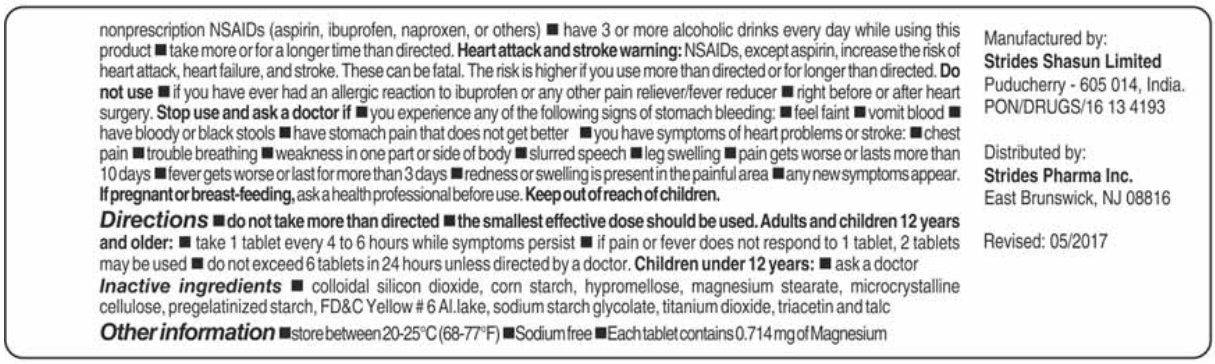

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Font : Helvetica	Text : 6 pt
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IBUPROFEN IMMEDIATE RELEASE

ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59556-856
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, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	ORANGE	**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:59556-856-41	1 in 1 CARTON	04/04/2011	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59556-856-25	1 in 1 CARTON	04/04/2011	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:59556-856-06	1 in 1 CARTON	04/04/2011	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:59556-856-44	1 in 1 CARTON	04/04/2011	
4		165 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:59556-856-07	1 in 1 CARTON	04/04/2011	
5		500 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:59556-856-08	1 in 1 CARTON	04/04/2011	
6		1000 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:59556-856-46	1000 in 1 BAG; Type 0: Not a Combination Product	04/04/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091355	04/04/2011	

IBUPROFEN IMMEDIATE RELEASE

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59556-855
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, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
TALC (UNII: 7SEV7J4R1U)	

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:59556-855-41	1 in 1 CARTON	04/04/2011	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59556-855-25	1 in 1 CARTON	04/04/2011	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:59556-855-06	1 in 1 CARTON	04/04/2011	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:59556-855-44	1 in 1 CARTON	04/04/2011	
4		165 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:59556-855-07	1 in 1 CARTON	04/04/2011	
5		500 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:59556-855-08	1 in 1 CARTON	04/04/2011	
6		1000 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:59556-855-46	1000 in 1 BAG; Type 0: Not a Combination Product	04/04/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091355	04/04/2011	

Labeler - Strides Pharma Inc. (078868278)

Establishment

Name	Address	ID/FEI	Business Operations
Strides Shasun Limited		871402375	ANALYSIS(59556-855, 59556-856) , MANUFACTURE(59556-855, 59556-856)

Revised: 5/2017 Strides Pharma Inc.