

IBU- ibu tablet DirectRX

IBU

Boxed Warning

BOXED WARNING

Cardiovascular Risk

- NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk (See [WARNINGS](#)).
- IBU tablets are contraindicated for treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery (See [WARNINGS](#)).

Gastrointestinal Risk

- NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events. (See [WARNINGS](#)).

[CLOSE](#)

Description

-

Clinical Pharmacology

-

Indications and Usage

-

Contraindications

-

Warnings

-

Precautions

-

Adverse Reactions

-

Overdosage

-

Dosage and Administration

-

How Supplied

-

Medication Guide

-

Package Label

D

Mfg By: Dr. Reddy's Laboratories LA, LLC
Shreveport, LA 71106
NDC 65111-684-05

12/29/2016 Mfg Lot:

IBUPROFEN 800mg 90 Tabs

Generic For: **MOTRIN**
Each tablet contains: Ibuprofen, USP 800mg

Lot# Prod# 621-90 Discard After: 08/18

Packaged and Distributed By: **DIRECT Rx**

Alpharetta, GA 30005

AE0GT

Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.
RX ONLY-KEEP OUT OF REACH OF CHILDREN
Dosage: See package insert. Store between 68-77 degrees F

M

NDC 61919-621-90

May cause drowsiness or dizziness.

IBUPROFEN 800mg
NDC 61919-621-90 90 Tabs
Lot Exp Date 08/18
Mfg NDC 55111-684-05

IBUPROFEN 800mg
NDC 61919-621-90 90 Tabs
Lot Exp Date 08/18
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NDC 61919-621-90 90 Tabs
Lot Exp Date 08/18
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D

Mfg By: Dr. Reddy's Laboratories LA, LLC
Shreveport, LA 71106
NDC 55111-684-05

SAMPLE 4/30/2019 SAMPLE

IBUPROFEN 800mg 30 Tabs

Generic For: **MOTRIN**
Each tablet contains: Ibuprofen, USP 800mg

Lot# SAMPLE Prod# 4210-800-30 Discard After: 1/31/21
61919-621-30 SAMPLE
1/31/21 DAWSONVILLE, AVVRC GA 30534

Packaged and Distributed By: **DIRECT Rx**

AVVRC

Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.
RX ONLY-KEEP OUT OF REACH OF CHILDREN
Dosage: See package insert. Store between 68-77 degrees F

M

NDC 61919-621-30

IBUPROFEN 800mg
NDC 61919-621-30 30 Tabs
Lot SAMPLE Exp Date 01/21
Mfg NDC 55111-684-05

IBUPROFEN 800mg
NDC 61919-621-30 30 Tabs
Lot SAMPLE Exp Date 01/21
Mfg NDC 55111-684-05

IBUPROFEN 800mg
NDC 61919-621-30 30 Tabs
Lot SAMPLE Exp Date 01/21
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IBUPROFEN 800mg
NDC 61919-621-30 30 Tabs
Lot SAMPLE Exp Date 01/21
Mfg NDC 55111-684-05

IBU

ibu tablet

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:6 19 19 -6 21(NDC:55111-684)	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)		IBUPROFEN	800 mg	
Inactive Ingredients				
Ingredient Name			Strength	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYDEXTROSE (UNII: VH2XOU12IE)				
Product Characteristics				
Color	white	Score	no score	
Shape	CAPSULE	Size	9mm	
Flavor		Imprint Code	8I	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:6 19 19 -6 21-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/29/2015	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA075682		12/29/2015	

Labeler - DirectRX (079254320)

Registrant - DirectRX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DirectRX		079254320	repack(6 19 19-6 21)

Revised: 5/2019

DirectRX