**IBU- ibu tablet**
**DirectRX**

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**IBU**

**Boxed Warning**

BOXED WARNING

**Cardiovascular Risk**

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

**Gastrointestinal Risk**

- NSAIDS cause an increased risk of serious gastrointestinaladverse events including bleeding, ulceration, and perforationof the stomach or intestines, which can be fatal. These eventscan occur at any time during use and without warning symptoms.Elderly patients are at greater risk for serious gastrointestinalevents. (See WARNINGS).

CLOSE

## Description

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## Clinical Pharmacology

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## Indications and Usage

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## Contraindications

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## Warnings

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## Precautions

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## Adverse Reactions

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## Overdosage

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## Dosage and Administration

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## How Supplied

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## Medication Guide

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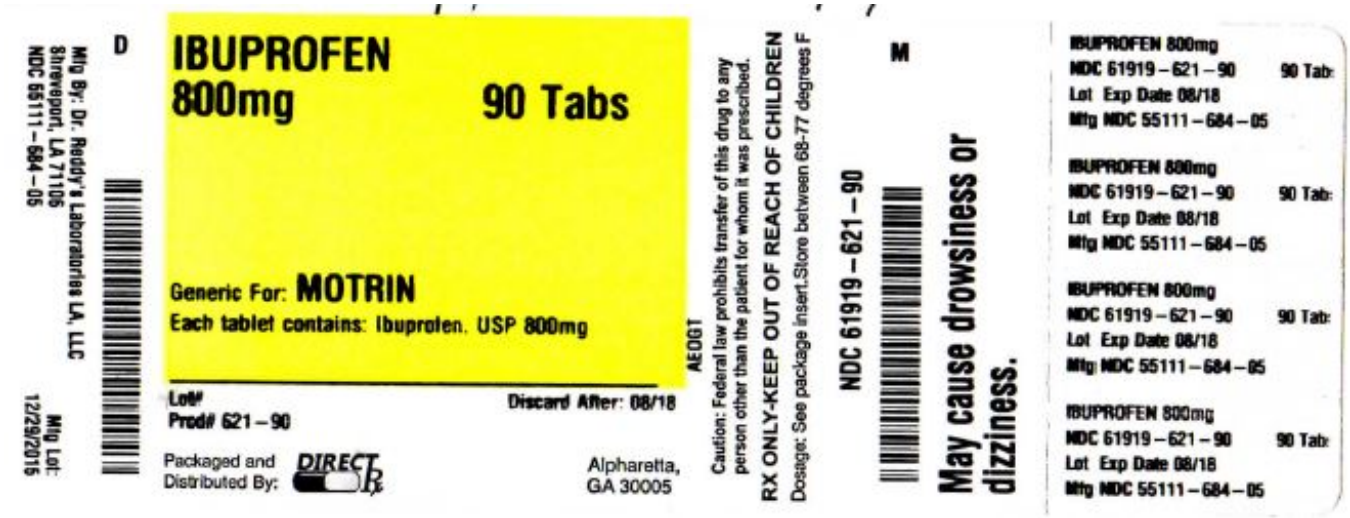
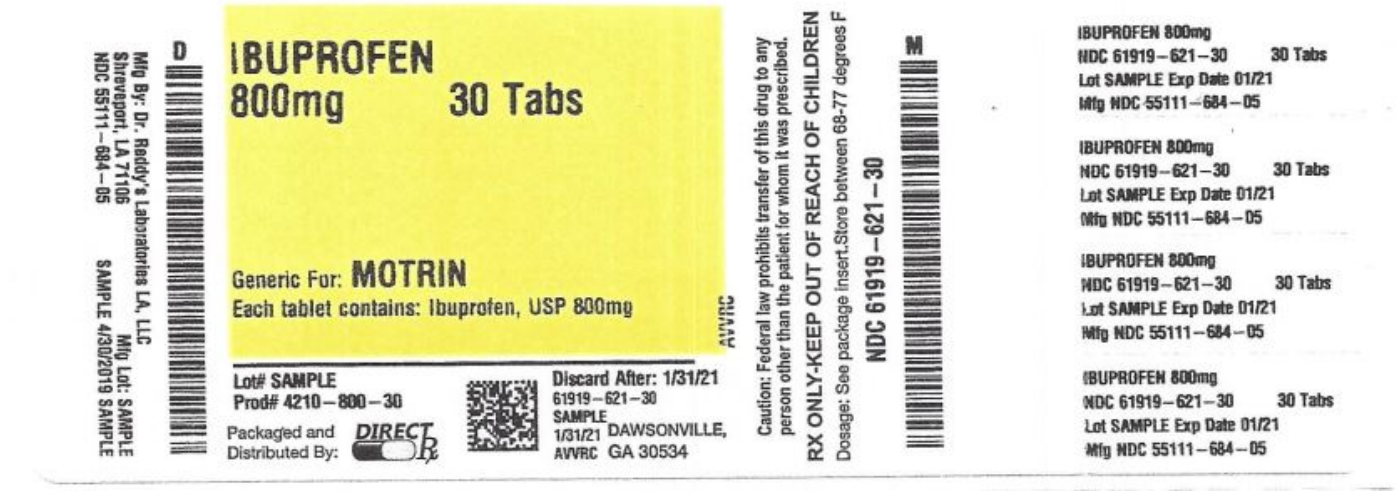
## Package Label




| **IBU** |
| --- |
| ibu tablet |

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:61919-621(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:61919-621-90 | 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(61919-621) |

Revised: 5/2019