**IBUPROFEN- ibuprofen tablet, film coated**
**Major Pharmaceuticals**

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**Major 44-438-DSP**

### *Active ingredient (in each white tablet)*

Ibuprofen USP, 200 mg (NSAID)*
*nonsteroidal anti-inflammatory drug

### *Purpose*

Pain reliever/fever reducer

### *Uses*

- temporarily relieves minor aches and pains due to:
  - backache
  - menstrual cramps
  - toothache
  - muscular aches
  - headache
  - the common cold
  - minor pain of arthritis
- temporarily reduces fever

### *Warnings*

**Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- rash
- hives
- shock
- facial swelling
- asthma (wheezing)
- blisters
- skin reddening

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

- take more or for a longer time than directed
- take a blood thinning (anticoagulant) or steroid drug
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or nonprescription NSAIDs [aspirin,

ibuprofen, naproxen, or others]
- are age 60 or older

**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 any other pain reliever/fever reducer
- right before or after heart surgery

**Ask a doctor before use if**
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you are taking a diuretic
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you have problems or serious side effects from taking pain relievers or fever reducers

**Ask a doctor or pharmacist before use if you are**
- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

**When using this product**
- take with food or milk if stomach upset occurs

**Stop use and ask a doctor if**
- you experience any of the following signs of stomach bleeding:
  - feel faint
  - have bloody or black stools
  - vomit blood
  - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
  - chest pain
  - slurred speech
  - leg swelling
  - trouble breathing
  - weakness in one part or side of body
- 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 at 20

weeks or later in 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.

***Directions***

- **do not take more than directed**
- **the smallest effective dose should be used**
- adults and children 12 years and over: 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

***Other information***

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store between 20°-25°C (68°-77°F)
- avoid excessive heat 40°C (104°F)

***Inactive ingredients***

colloidal silicon dioxide, corn starch, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, triacetin

***Questions or comments?***

**Call 1-800-426-9391** 8:30 AM-4:00 PM ET, Monday-Friday

***Principal Display Panel***

NDC 0904-7914-61

**MAJOR®**

**Unit Dose**

**IBUPROFEN**
TABLETS, USP
Pain Reliever/Fever Reducer
**(NSAID)**

**200 mg each**

**Institutional Dispensing Only**
**100 TABLETS**

50844 REV1221D43812

Distributed by:
MAJOR® PHARMACEUTICALS
Indianapolis, IN 46268
(800) 616-2471
www.majorpharmaceuticals.com

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**


**Major 44-438**

# IBUPROFEN

ibuprofen tablet, film coated

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0904-7914 |
| **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) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **ANHYDROUS LACTOSE** (UNII: 3SY5LH9PMK) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYDEXTROSE** (UNII: VH2XOU12IE) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |
| **SODIUM STARCH GLYCOLATE TYPE A POTATO** (UNII: 5856J3G2A2) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **TRIACETIN** (UNII: XHX3C3X673) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | white | **Score** | no score |
| **Shape** | ROUND | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | 44;438 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0904-7914-61 | 10 in 1 CARTON | 03/01/1999 | |
| **1** | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **2** | NDC:0904-7914-80 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 03/01/1999 | 11/26/2021 |
| **3** | NDC:0904-7914-51 | 1 in 1 CARTON | 03/01/1999 | 02/01/2024 |
| **3** | | 50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| **4** | NDC:0904-7914-59 | 1 in 1 CARTON | 03/01/1999 | 02/01/2024 |
| **4** | | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA075139 | 03/01/1999 | |

## Labeler - Major Pharmaceuticals (191427277)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 038154464 | pack(0904-7914) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867837 | manufacture(0904-7914) , pack(0904-7914) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867894 | manufacture(0904-7914) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 967626305 | pack(0904-7914) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 117025878 | manufacture(0904-7914) |

Revised: 4/2025 Major Pharmaceuticals