

**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**

**KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION**

**Drug Facts**  
Active ingredient (in each white tablet) **Purpose**  
Ibuprofen USP, 200 mg (NSAID)\* Pain reliever/fever reducer  
\*nonsteroidal anti-inflammatory drug

**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) ■ hives ■ skin redness  
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 have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke ■ you are taking a diuretic  
■ 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 the benefit of aspirin ■ taking any other drug

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

**Drug Facts (continued)**  
Stop use and ask a doctor if ■ you experience any of the following signs of stomach bleeding: ■ hiccups ■ 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.

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■ the smallest effective dose should be used  
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■ children under 12 years: ask a doctor

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

**Inactive ingredients** colloidal silicon dioxide, corn starch, hydroxypropylcellulose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, titanium dioxide

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

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Rev. 03/23 M-17 Re-order No. 301559

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UNIT IS TORN, BROKEN OR SHOWS  
ANY SIGNS OF TAMPERING**

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**MAJOR®**  
Unit Dose  
**IBUPROFEN**  
TABLETS, USP  
Pain Reliever/Fever Reducer  
(NSAID)  
200 mg each  
100 TABLETS

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NDC 0904-7914-61

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B-1212-438-12-DSP  
REV1221D43812

**Major 44-438**

## **IBUPROFEN**

ibuprofen tablet, film coated

### **Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-7914
<b>Route of Administration</b>	ORAL		

<b>Active Ingredient/Active Moiety</b>		
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

<b>Inactive Ingredients</b>	
<b>Ingredient Name</b>	<b>Strength</b>
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	

<b>Product Characteristics</b>			
<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	44;438
<b>Contains</b>			

<b>Packaging</b>				
#	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: 4/2024

Major Pharmaceuticals