

**IBUPROFEN- ibuprofen tablet, film coated**  
**GREAT LAKES WHOLESAL, MARKETING, & SALES, INC.**

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**Healthcare 44-291 Delisted**

***Active ingredient (in each brown tablet)***

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

***Purpose***

Pain reliever/fever reducer

***Uses***

- temporarily relieves minor aches and pains due to:
  - menstrual cramps
  - toothache
  - the common cold
  - backache
  - headache
  - muscular aches
  - 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:

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

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
- are age 60 or older
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]

- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product

**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**

- 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
- stomach bleeding warning applies to you
- 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

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 (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 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***

- store between 20°-25°C (68°-77°F)
- avoid excessive heat 40°C (104°F)
- see end flap for expiration date and lot number

***Inactive ingredients***

carnauba wax, colloidal silicon dioxide, corn starch, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide

***Questions or comments?***

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

**Principal Display Panel**

**HEALTHCARE™**

**NDC 64092-200-50**

*†Compare to Active  
Ingredient in Advil® Tablets*

**Ibuprofen**

*Ibuprofen Tablets USP, 200 mg  
Pain Reliever and Fever Reducer (NSAID)*

50 Tablets

**HEALTHCARE GUARANTEE**


If you are not completely satisfied with this product, regardless of reason,

return your unused portion to Great Lakes Wholesale for a full refund

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

†This product is not manufactured or distributed by Wyeth LLC, owner of the registered trademark Advil® Tablets. 50844 REV0618F29115

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<p><b>No Print Area</b> <b>Lot no. &amp; Exp. Date</b></p> <p>7 92215180202 8</p> <p><b>TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING</b></p> <p><b>HEALTHCARE GUARANTEE:</b> If you are not completely satisfied with this product, regardless of reason, return your unused portion to Great Lakes Wholesale for a full refund.</p>	<p><b>HEALTHCARE</b></p> <p><b>Ibuprofen</b> Ibuprofen Tablets USP, 200 mg (NSAID) Pain Reliever and Fever Reducer</p> <p><b>50 Tablets</b></p> <p>NDC 64092-200-50 Compare to Active Ingredient in Advil® Tablets</p> 	<p><b>Drug Facts (continued)</b> microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide</p> <p><b>Questions or comments?</b> Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday</p> <p>This product is not manufactured or distributed by Wyeth LLC, owner of the registered trademark Advil® Tablets. 50844 REV0618F29115 Distributed by: Great Lakes Wholesale &amp; Marketing L.L.C. 3729 Patterson Ave., S.E., Grand Rapids, MI 49512 www.glwholesale.com</p>
<p>B-0616-291-15 REV0618F29115</p>	<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>• pain gets worse or lasts more than 10 days</li> <li>• fever gets worse or lasts more than 3 days</li> <li>• redness or swelling is present in the painful area</li> <li>• any new symptoms appear</li> </ul> <p>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 (1-800-222-1222) right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>• do not take more than directed</li> <li>• the smallest effective dose should be used</li> <li>• adults and children 12 years and over: take 1 tablet every 4 to 6 hours while symptoms persist</li> <li>• if pain or fever does not respond to 1 tablet, 2 tablets may be used</li> <li>• do not exceed 6 tablets in 24 hours, unless directed by a doctor</li> <li>• children under 12 years: ask a doctor</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>• store between 20°-25°C (68°-77°F)</li> <li>• avoid excessive heat 40°C (104°F)</li> <li>• see end flap for expiration date and lot number.</li> </ul> <p><b>Inactive ingredients</b> carnauba wax, colloidal silicon dioxide, corn starch, hypromellose, lactose anhydrous, magnesium stearate.</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Heart attack and stroke warning:</b> 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.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>• if you have ever had an allergic reaction to any other pain reliever/fever reducer</li> <li>• right before or after heart surgery</li> </ul> <p><b>Ask a doctor before use if</b></p> <ul style="list-style-type: none"> <li>• you have a history of stomach problems, such as heartburn</li> <li>• you are taking a diuretic</li> <li>• you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke</li> <li>• stomach bleeding warning applies to you</li> <li>• you have problems or serious side effects from taking pain relievers or fever reducers</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are</b></p> <ul style="list-style-type: none"> <li>• under a doctor's care for any serious condition</li> <li>• taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin</li> <li>• taking any other drug</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>• take with food or milk if stomach upset occurs</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>• you experience any of the following signs of stomach bleeding:             <ul style="list-style-type: none"> <li>• feel faint</li> <li>• vomit blood</li> <li>• have bloody or black stools</li> </ul> </li> <li>• you have stomach pain that does not get better</li> <li>• you have symptoms of heart problems or stroke:             <ul style="list-style-type: none"> <li>• chest pain</li> <li>• leg swelling</li> <li>• slurred speech</li> </ul> </li> <li>• weakness in one part or side of body</li> </ul>
<p><b>Drug Facts</b> (in each brown tablet)</p> <p>Ibuprofen USP, 200 mg (NSAID) * ..... Pain reliever/fever reducer * nonsteroidal anti-inflammatory drug</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>• temporarily relieves minor aches and pains due to:             <ul style="list-style-type: none"> <li>• menstrual cramps</li> <li>• toothache</li> <li>• the common cold</li> <li>• backache</li> <li>• headache</li> <li>• muscular aches</li> <li>• minor pain of arthritis</li> </ul> </li> <li>• temporarily reduces fever</li> </ul> <p><b>Warnings</b></p> <p><b>Allergy alert:</b> ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:</p> <ul style="list-style-type: none"> <li>• skin redness</li> <li>• facial swelling</li> <li>• rash</li> <li>• asthma (wheezing)</li> <li>• stock</li> <li>• hives</li> <li>• blisters</li> </ul> <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p><b>Stomach bleeding warning:</b> 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</p> <ul style="list-style-type: none"> <li>• take a blood thinning (anticoagulant) or steroid drug</li> <li>• are age 60 or older</li> <li>• take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)</li> <li>• have had stomach ulcers or bleeding problems</li> <li>• have 3 or more alcoholic drinks every day while using this product</li> </ul>	<p><b>Drug Facts</b> (continued)</p> <p><b>Heart attack and stroke warning:</b> 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.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>• if you have ever had an allergic reaction to any other pain reliever/fever reducer</li> <li>• right before or after heart surgery</li> </ul> <p><b>Ask a doctor before use if</b></p> <ul style="list-style-type: none"> <li>• you have a history of stomach problems, such as heartburn</li> <li>• you are taking a diuretic</li> <li>• you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke</li> <li>• stomach bleeding warning applies to you</li> <li>• you have problems or serious side effects from taking pain relievers or fever reducers</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are</b></p> <ul style="list-style-type: none"> <li>• under a doctor's care for any serious condition</li> <li>• taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin</li> <li>• taking any other drug</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>• take with food or milk if stomach upset occurs</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>• you experience any of the following signs of stomach bleeding:             <ul style="list-style-type: none"> <li>• feel faint</li> <li>• vomit blood</li> <li>• have bloody or black stools</li> </ul> </li> <li>• you have stomach pain that does not get better</li> <li>• you have symptoms of heart problems or stroke:             <ul style="list-style-type: none"> <li>• chest pain</li> <li>• leg swelling</li> <li>• slurred speech</li> </ul> </li> <li>• weakness in one part or side of body</li> </ul>	<p><b>Drug Facts</b> (continued)</p> <p>microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide</p> <p><b>Questions or comments?</b> Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday</p> <p>This product is not manufactured or distributed by Wyeth LLC, owner of the registered trademark Advil® Tablets. 50844 REV0618F29115 Distributed by: Great Lakes Wholesale &amp; Marketing L.L.C. 3729 Patterson Ave., S.E., Grand Rapids, MI 49512 www.glwholesale.com</p>

## Healthcare 44-291

### IBUPROFEN

ibuprofen tablet, film coated

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64092-200
<b>Route of Administration</b>	ORAL		

#### Active Ingredient/Active Moiety

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

#### Inactive Ingredients

Ingredient Name	Strength
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<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>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

#### Product Characteristics

<b>Color</b>	brown	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	44;291
<b>Contains</b>			

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64092-200-50	1 in 1 CARTON	05/24/1988	10/31/2024
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:64092-200-30	1 in 1 CARTON	05/24/1988	10/31/2024

2	30 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	ANDA075010	05/24/1988	10/31/2024

**Labeler -** GREAT LAKES WHOLESAL, MARKETING, & SALES, INC. (361925498)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(64092-200)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(64092-200)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(64092-200)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(64092-200) , pack(64092-200)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(64092-200)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(64092-200)

Revised: 7/2023

GREAT LAKES WHOLESAL, MARKETING, & SALES, INC.