

**IBUPROFEN- ibuprofen tablet, film coated**  
**DOLGENCORP, LLC**

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**Ibuprofen Tablets USP, 200 mg**

***DRUG FACTS***

***ACTIVE INGREDIENT***

***(in each orange caplet)***

Ibuprofen USP, 200 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

***PURPOSE***

Pain reliever/fever reducer

***USES***

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

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

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:

- are age 60 or older

- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing perscription or nonperscription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time 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 problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease or asthma
- you are taking a diuretic

#### **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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

#### **Stop use and ask a doctor if**

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- 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 right away.

#### ***DIRECTIONS***

- **do not take more than directed**

- **the smallest effective dose should be used**
- do not take longer than 10 days, unless directed by a doctor (see WARNINGS )
- 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 at controlled room temperature
- avoid excessive heat above 40°C (104°F)
- see end flap or expiration date and lot number

#### ***INACTIVE INGREDIENTS***

carnauba wax, cellulose, corn starch, FD&C yellow #6, fumed silica gel, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

#### ***Questions or comments?***

call 1-800-426-9391

#### **PRODUCT PACKAGING**

The product packaging shown below represents a sample of that currently in use. Additional packaging may also be available.

**DG**

**health**

Compare to active ingredient of Motrin® IB†

**Ibuprofen**

Tablets 200 mg

Pain Reliever/Fever Reducer (NSAID)

**SEE NEW WARNINGS INFORMATION**

**100**

**Coated Tablets**

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

50844 REV1209B39212

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100 MISSION RIDGE

GOODLETTSVILLE, TN 37072



## IBUPROFEN

ibuprofen tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:559 10-392
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Ibuprofen (UNII: WK2XYI10 QM) (Ibuprofen - UNII:WK2XYI10 QM)	Ibuprofen	200 mg

Inactive Ingredients				
Ingredient Name			Strength	
Carnauba Wax (UNII: R12CBM0EIZ)				
Powdered Cellulose (UNII: SMD1X3XO9M)				
Starch, Corn (UNII: O8232NY3SJ)				
Fd&c Yellow No. 6 (UNII: H77VEI93A8)				
Hypromellose (UNII: 3NXW29V3WO)				
Lactose (UNII: J2B2A4N98G)				
Magnesium Stearate (UNII: 70097M6I30)				
Polydextrose (UNII: VH2XOU12IE)				
Polyethylene Glycol (UNII: 3WJQ0SDW1A)				
Stearic Acid (UNII: 4ELV7Z65AP)				
Titanium Dioxide (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	ORANGE	Score	no score	
Shape	ROUND	Size	10mm	
Flavor		Imprint Code	44;392	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:559 10-392-12	1 in 1 CARTON		
1		100 in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA075139	03/02/1999		

**Labeler** - DOLGENCORP, LLC (068331990)

**Registrant** - L.N.K. International, Inc. (038154464)

Establishment			
Name	Address	ID/FEI	Business Operations
L.N.K. International, Inc.		038154464	MANUFACTURE