

**IBUPROFEN - ibuprofen tablet, coated**  
**Weeks & Leo Co., Inc.**

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**ACTIVE INGREDIENT(S)**

Ibuprofen 200 mg (NSAID)\*

\* nonsteroidal anti-inflammatory drug

**PURPOSE**

Pain reliever / fever reducer

**USE(S)**

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

**WARNINGS**

**Allergy alerts:** Ibuprofen may cause a severe allergy reaction, especially in people allergic to aspirin.

Symptoms may include:

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

If an allergic reaction occurs, stop use and seek medical help right away.

**Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. The chance is higher if you:

- are age 60 or older
- have bad stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drug containing prescription NSAID (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- the 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**

you have

- problems or serious side effects from taking pain relievers or fever reducers
- stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain
- ulcers
- bleeding problems
- high blood pressure
- heart or kidney disease
- taken a diuretics
- reached age 60 or older

### **ASK A DOCTOR OR PHARMACIST BEFORE USE IF**

you are

- taking any other drugs containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- under a doctor's care for any serious condition
- taking aspirin for heart attacks 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
- long term continuous use may increase the risk of heart attack or stroke

### **STOP USE AND ASK DOCTOR IF**

- you feel faint, vomit blood, or have bloody or black stools.

These are signs of stomach bleeding.

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- stomach pain or upset gets worse or lasts
- redness or swelling is present in painful area
- any new symptoms appear

### **PREGNANCY/BREASTFEEDING**

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 a 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. (1-800-222-1222)

### **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 older	<ul style="list-style-type: none"> <li>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> </ul>
Children under 12 years	<ul style="list-style-type: none"> <li>ask a doctor</li> </ul>

### STORAGE

- Store between 20-25°C (68-77 °F).
- Do not use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.**

### INACTIVE INGREDIENTS

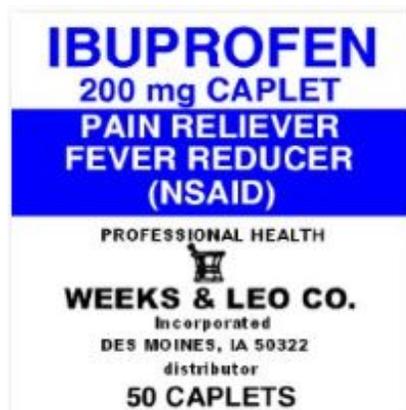
colloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinised starch, talc, titanium dioxide.

### PRINCIPAL DISPLAY PANEL

**Carton Label PDP**

**Ibuprofen 200mg CAPLET**

**PAIN RELIEVER/ FEVER REDUCER (NSAID)**



### Drug Facts (continued)

- 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 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 prescription or nonprescription 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**

- the stomach bleeding warning applies to you
- you have problems or serious side effects from taking

### Drug Facts (continued)

- pain relievers or fever reducers
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, kidney disease, liver cirrhosis
- you are taking a diuretic
- you have asthma

**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**

- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.

### Drug Facts (continued)

- 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 occur

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

### Drug Facts (continued)

adults and children 12 years and older	■ take 1 caplet every 4 to 6 hours while symptoms persist	■ if pain or fever does not respond to 1 caplet, 2 caplets may be used	■ do not exceed 6 caplets 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)

### Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

# IBUPROFEN

ibuprofen tablet, coated

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11383-151
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
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	

## Product Characteristics

Color	BROWN	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	117
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11383-151-50	1 in 1 CARTON		
1		50 in 1 BOTTLE		
2	NDC:11383-151-11	1 in 1 CARTON		
2		100 in 1 BOTTLE		
3	NDC:11383-151-21	1 in 1 CARTON		
3		200 in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091239	05/17/2013	

**Labeler** - Weeks & Leo Co., Inc. (005290028)

**Registrant** - Weeks & Leo Co., Inc. (005290028)

**Establishment**

Name	Address	ID/FEI	Business Operations
Marksans Pharma Limited		925822975	MANUFACTURE(11383-151)

Revised: 5/2013

Weeks & Leo Co., Inc.