# MOTRIN IB- ibuprofen tablet, film coated Lil' Drug Store Products, Inc.

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Motrin ® IB

**Drug Facts** 

# Active ingredient (in each caplet)

Ibuprofen 200 mg (NSAID) <sup>1</sup>

1 nonsteroidal anti-inflammatory drug

### **Purposes**

Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - minor pain of arthritis
  - toothache
  - backache
  - the common cold
  - menstrual cramps
- 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 chances are 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 ibuprofen or 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
- the 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, or kidney disease
- you have asthma
- you are taking a diuretic

### Ask a doctor or pharmacist before use if you are

- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any serious condition
- 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. (1-800-222-1222)

#### **Directions**

- do not take more than directed
- the smallest effective dose should be used

adults and children 12 years and older	<ul> <li>take 1 caplet every 4         to 6 hours while         symptoms persist</li> <li>if pain or fever does         not respond to 1         caplet, 2 caplets may         be used</li> <li>do not exceed 6         caplets in 24 hours,         unless directed by a         doctor</li> </ul>
children under 12 years	■ ask a doctor

#### Other information

- read all warnings and directions before use
- store at 20-25°C (68-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- do not use if pouch is torn or damaged

# Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, iron oxides, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, stearic acid, talc, titanium dioxide

### Questions?

Call **1-877-895-3665** (toll-free) or **215-273-8755** (collect) or visit www.motrin.com Distributed by:

# JOHNSON & JOHNSON CONSUMER INC.

McNeil Consumer Healthcare Division

Fort Washington, PA 19034 USA

Repackaged and distributed by Convenience Valet ®, Glendale Heights, IL 60139

# PRINCIPAL DISPLAY PANEL - 200 mg Caplet Pouch Package

minimum annual

\$250,000

**Donation** 

See details on back.

Children's

Miracle Network

Hospitals ®

New Information: Read Entire Label

Motrin ® IB

Ibuprofen Tablets USP, 200 mg

Pain Reliever / Fever Reducer (NSAID)

**FPO** 

2 Pouches

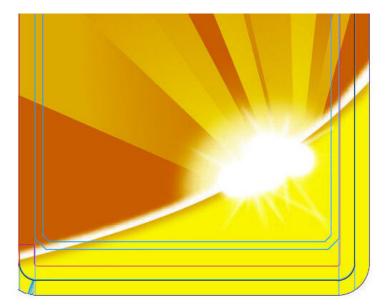
of 2 Coated

Caplets\* Each

\*Capsule-Shaped Tablets

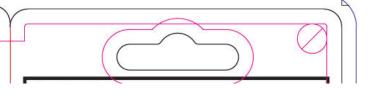


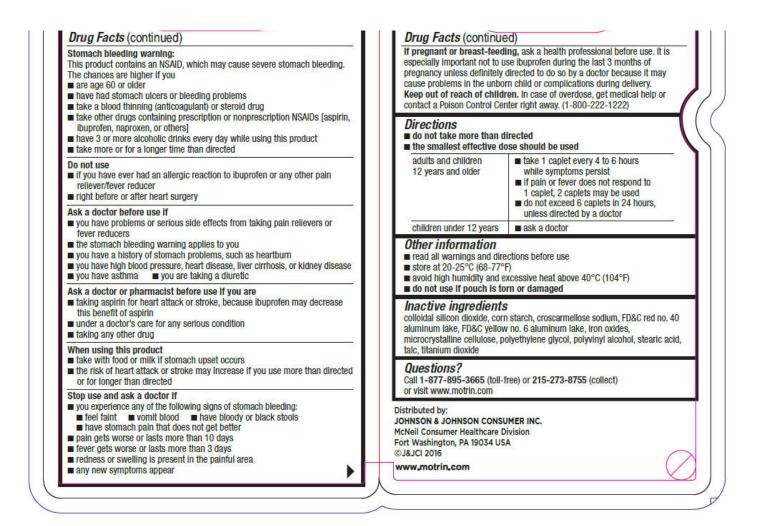












# PRINCIPAL DISPLAY PANEL-200mg Caplet Pouch 6ct Package

New Information: Read Entire Label

Motrin ® IB

Ibuprofen Tablets USP, 200 mg

Pain Reliever/Fever Reducer (NSAID)

#### 3 POUCHES OF 2 COATED CAPLETS\* EACH

\*Capsule-Shaped Tablets



# PRINCIPAL DISPLAY PANEL-200mg Caplet Pouch 30ct Box

Motrin ® IB

Ibuprofen Tablets USP, 200 mg

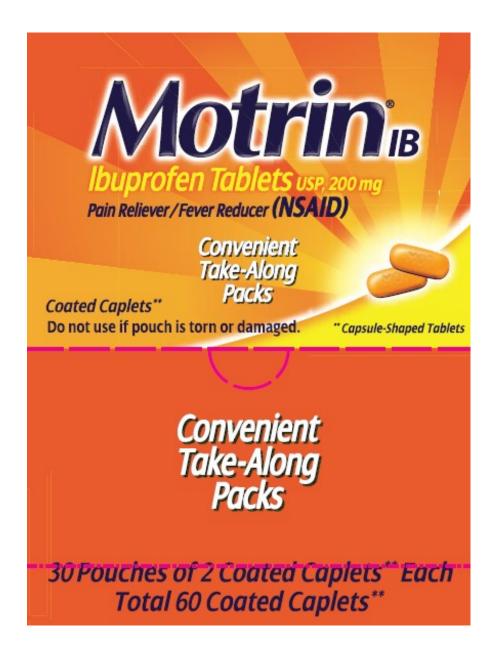
Pain Reliever/Fever Reducer (NSAID)

Convenient Take-Along Packs

Coated Caplets\*\* Do not use if pouch is torn or damaged.

\*\*Capsule-Shaped Tablets

30 POUCHES OF 2 COATED CAPLETS\* EACH



#### **Mortin CVP 4 Count Carton**

See Revised Warnings

Motrin ® IB

Ibuprofen Tablets USP, 200 mg

Pain Reliever/Fever Reducer (NSAID)

[caplet image]

4 Coated Caplets\*\*

2 POUCHES OF 2 CAPLETS EACH

\*\*Capsule-Shaped Tablets

**CVP** 

**HEALTH** 



# **MOTRIN IB**

ibuprofen tablet, film coated

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Prod	IUCT	Intori	mation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:29485-7006

**Route of Administration** ORAL

# **Active Ingredient/Active Moiety**

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Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients	
Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B710)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics					
Color	orange	Score	no score		
Shape	OVAL	Size	16mm		
Flavor		Imprint Code	Motrin;IB		
Contains					

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
<b>1</b> NDC:29485-7006-3	30 in 1 BOX	05/09/2017	12/31/2025			
1	2 in 1 POUCH; Type 0: Not a Combination Product					

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA019012	05/09/2017	12/31/2025	

# **MOTRIN IB**

ibuprofen tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29485-7938	
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

SHELLAC (UNII: 46N107B710)

STEARIC ACID (UNII: 4ELV7Z65AP)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics				
Color	orange	Score	no score	
Shape	OVAL	Size	16mm	
Flavor		Imprint Code	Motrin;IB	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:29485- 7938-6	3 in 1 PACKAGE	02/07/2017	01/23/2026		
1		2 in 1 POUCH; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA019012	02/06/2017	01/23/2026	

# **MOTRIN IB**

ibuprofen tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29485-1465	
Route of Administration	ORAL			

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

Inactive Ingredients	
Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B710)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	orange	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	Motrin;IB
Contains			

P	Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:29485- 1465-4	2 in 1 PACKAGE	08/01/2000	10/25/2025		
1		2 in 1 POUCH; Type 0: Not a Combination Product				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019012	08/01/2000	10/25/2025

# **MOTRIN IB**

ibuprofen tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29485-6512	
Route of Administration	ORAL			

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

Inactive Ingredients	
Ingredient Name	Strength

CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B710)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics					
Color	orange	Score	no score		
Shape	OVAL	Size	16mm		
Flavor		Imprint Code	Motrin;IB		
Contains					

P	Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:29485- 6512-4	2 in 1 CARTON	08/25/2017	12/31/2025				
1		2 in 1 POUCH; Type 0: Not a Combination Product						

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
NDA	NDA019012	08/25/2017	12/31/2025		

# Labeler - Lil' Drug Store Products, Inc. (093103646)

Revised: 12/2023 Lil' Drug Store Products, Inc.