

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

Motrin IB®

Drug Facts

Active ingredient (in each caplet)

Ibuprofen 200 mg (NSAID)¹

¹ nonsteroidal anti-inflammatory drug

Purpose

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 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

- 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**

-
- take 1 caplet every 4 to 6 hours while symptoms

adults and children 12 years and older	<p>persist</p> <ul style="list-style-type: none"> ▪ 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	<ul style="list-style-type: none"> ▪ ask a doctor

Other information

- store between 20 - 25°C (68 - 77°F)
- **do not use if carton or pouch is open or torn**
- see bottom panel for lot number and expiration date

Inactive ingredients

carnauba wax, colloidal silicon dioxide, corn starch, FD&C yellow #6, hypromellose, iron oxide, magnesium stearate, polydextrose, polyethylene glycol, pregelatinized starch, propylene glycol, shellac, stearic acid, titanium dioxide

Questions or comments?

Call 1-877-895-3665: weekdays 8:00 AM to 8:00 PM EST

Repackaged and distributed by: Lil' Drug Store Products, Inc.
1201 Continental Place NE, Cedar Rapids, IA 52402

PRINCIPAL DISPLAY PANEL - 4 Caplet Carton

See New Warnings Information

Motrin IB[®]

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

****Capsule-Shaped Tablets***

***4 COATED
CAPLETS****

***Lil'
Drug Store[®]***

See New Warnings Information

Motrin[®] IB

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



*Capsule-Shaped Tablets

4 COATED
CAPLETS*



Code 128
1464

4 COATED
CAPLETS*

Motrin[®] IB

Important: Read all product information before using.
Keep this box for important information.

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*nonsteroidal anti-inflammatory drug	

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LIFT PANEL FOR CONTINUED DRUG FACTS

Drug Facts (continued)

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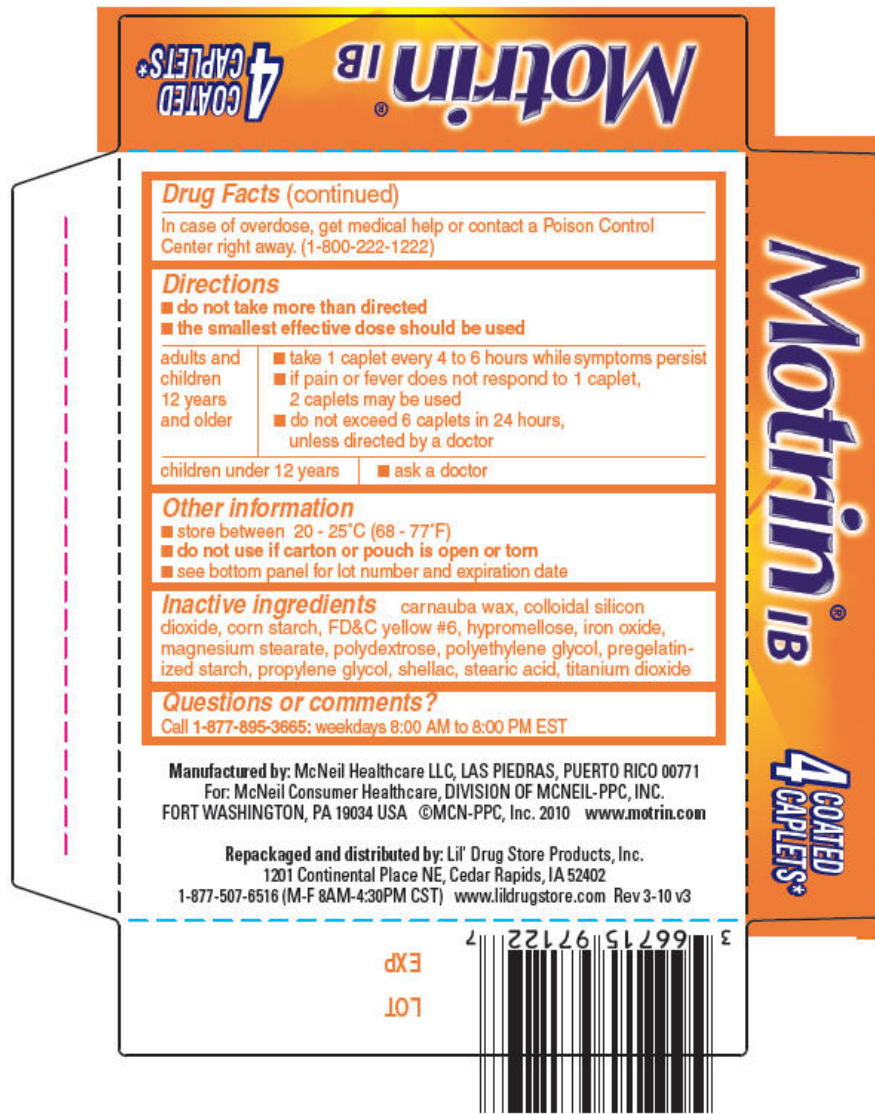
Drug Facts (continued)

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MOTRIN IB

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-9712(NDC:50580-110)
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)	
hypromelloses (UNII: 3NXW29V3WO)	
ferric oxide red (UNII: 1K09F3G675)	
magnesium stearate (UNII: 70097M6I30)	
polydextrose (UNII: VH2XOU12IE)	
polyethylene glycols (UNII: 3WJQ0SDW1A)	
propylene glycol (UNII: 6DC9Q167V3)	
shellac (UNII: 46N107B71O)	
stearic acid (UNII: 4ELV7Z65AP)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	OVAL	Size	14mm
Flavor		Imprint Code	Mo trin;IB
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715-9712-1	1 in 1 CARTON		
1		2 in 1 POUCH		
2	NDC:66715-9712-2	2 in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019012	05/10/2010	

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