



Labeling Format Information:				Fonts: HelveticaDF Cond Medium, Cond Bold, Cond Bold Italic			
Drug Facts:	NA pt	Body Text:	4.75 pt	Bullets:	3.75 pt	Horizontal Scale:	65%
Headers:	4.75 pt	Leading:	4.75 pt	Barlines:	NA pt	Average Kerning:	0
Subheaders:	4.75 pt	Drug Facts (cotinued):	NA pt	Hairlines:	NA pt		



(b) (4)





Labeling Format Information: Fonts: HelveticaDF Cond Medium, Cond Bold, Cond Bold Italic					
Drug Facts: NA pt	Body Text: 4.5 pt	Bullets: 3.5 pt	Horizontal Scale: 66%		
Headers: 4.5 pt	Leading: 4.5 pt	Barlines: NA pt	Average Kerning: 0		
Subheaders: 4.5 pt	Drug Facts (continued): 4.5 pt	Hairlines: NA pt			

(b) (4)

00000000

LOT

EXP

EXP

3

5058011060

7

See New Warnings

For Hospital and Government Use Only

NDC 50580-110-60

# Motrin<sup>®</sup> IB

**Ibuprofen Tablets USP, 200 mg**

Pain Reliever / Fever Reducer (NSAID)

60 Coated Caplets

\*Coated Caplet Tablets

00000000

Motrin<sup>®</sup> IB is a registered trademark of McNeil-PPC, Inc. © 2017 McNeil-PPC, Inc. All rights reserved.

**Labeling Format Information:** Fonts: HelveticaDF Cond Medium, Cond Bold, Cond Bold Italic

Drug Facts: 8.50 pt	Body Text: 6.00 pt	Bullets: 5.00 pt	Horizontal Scale: 72%
Headers: 8.00 pt	Leading: 6.50 pt	Barlines: 2.50 pt	
Subheaders: 6.00 pt	Drug Facts (cotinued): 8.00 pt	Hairlines: 0.50 pt	Average Kerning: 0

McNeil

Submission Artwork



00000000



LOT:  
EXP:

3 0045-0481-016



See New Warnings

# Motrin<sup>®</sup> IB

Ibuprofen Tablets USP, 200 mg

Pain Reliever/Fever Reducer (NSAID)

**100 Coated Caplets\***

\*Capsule-Shaped Tablets

NDC 50580-110-01

00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000



00000000




00000000



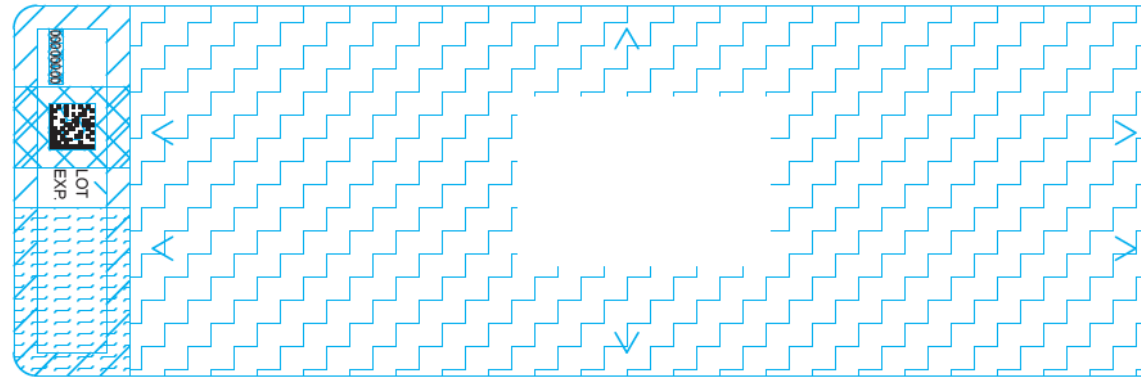


Labeling Format Information: Fonts: HelveticaDF Cond Medium, Cond Bold, Cond Bold Italic				
Drug Facts: NA pt	Body Text: 4.50 pt	Bullets: 3.50 pt	Horizontal Scale: 80%	
Headers: 5.00 pt	Leading: 4.65 pt	Barlines: NA pt	Average Kerning: 0	
Subheaders: 4.50 pt	Drug Facts (continued): NA pt	Hairlines: NA pt		



(b) (4)





BASE LABEL,  
PAGE 5  
GLUE APPLIED  
HERE

<p><b>Drug Facts (continued)</b></p> <p><b>Warnings</b> 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.</p> <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: 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.</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> if you have ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer right before or after heart surgery.</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Ask a doctor before use if:</b> 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, kidney disease, asthma, or had a stroke, you are taking a diuretic.</p> <p><b>Ask a doctor or pharmacist before use if you are:</b> taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin, under a doctor's care for any serious condition, taking any other drug.</p> <p><b>When using this product:</b> take with food or milk if stomach upset occurs.</p> <p><b>Stop use and ask a doctor if:</b> 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, you have symptoms of heart problems or stroke: chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling.</p>	<p><b>Drug Facts (continued)</b></p> <p>■ 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</p> <p><b>If pregnant or breast-feeding,</b> 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.</p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222).</p> <p><b>Directions</b> ■ do not take more than directed    ■ the smallest effective dose should be used</p> <p>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.</p> <p>children under 12 years: ask a doctor.</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Other information</b> ■ store between 20-25°C (68-77°F) ■ do not use if neck wrap or foil inner seal imprinted "SAFETY SEAL®" is broken or missing.</p> <p><b>Inactive ingredients:</b> cambeba wax, colloidal silicon dioxide, FD&amp;C yellow no. 6, hypromellose, iron oxide, magnesium stearate, modified starch, polydextrose, polyethylene glycol, pregelatinized starch, propylene glycol, shellac, stearic acid, titanium dioxide.</p> <p><b>Questions or comments?</b> Call 1-877-895-3665 (toll-free) or 215-273-8755 (collect).</p> <p><b>Motrin<sup>®</sup> IB</b> Ibuprofen Tablets USP, 200 mg</p> <p>Distributed by: <b>JOHNSON &amp; JOHNSON CONSUMER INC.</b> McNeil Consumer Healthcare Division Fort Washington, PA 19034 USA ©J&amp;JCI 2017</p> <p>00000000</p>
--	--	---	---

PAGE 2

PAGE 3

	<p><b>THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN</b></p> <p>See New W... <b>Mc</b> <b>Ibuprofen Tablets USP 200 mg</b> Pain Reliever / Fever Reducer (NSAID)</p> <p><b>225 Coated Caplets*</b></p> <p><b>VALUE SIZE!</b> NDC 50580-110-62</p> <p><b>OPEN TO READ DIRECTIONS AND ADDITIONAL DRUG FACTS INFORMATION</b> Do not use if neck wrap or foil inner seal imprinted "SAFETY SEAL®" is broken or missing.</p> <p>3 0045-0481-627</p> <p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active ingredient (in each caplet)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>ibuprofen 200 mg (NSAID)*</td> <td>Pain reliever/fever reducer</td> </tr> <tr> <td>*nonsteroidal anti-inflammatory drug</td> <td></td> </tr> </tbody> </table> <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>headache</li> <li>muscular aches</li> <li>minor pain of arthritis</li> <li>toothache</li> <li>backache</li> <li>the common cold</li> <li>menstrual cramps</li> <li>temporarily reduces fever</li> </ul> </li> </ul>	Active ingredient (in each caplet)	Purpose	ibuprofen 200 mg (NSAID)*	Pain reliever/fever reducer	*nonsteroidal anti-inflammatory drug	
Active ingredient (in each caplet)	Purpose						
ibuprofen 200 mg (NSAID)*	Pain reliever/fever reducer						
*nonsteroidal anti-inflammatory drug							

PAGE 4  
(GLUED TO BASE)

COVER, PAGE 1

**Labeling Format Information:** Fonts: HelveticaDF Cond Medium, Cond Bold, Cond Bold Italic

Drug Facts: 10.0 pt	Body Text: 6.00 pt	Bullets: 5.00 pt	Horizontal Scale: 85%
Headers: 8.00 pt	Leading: 6.50 pt	Barlines: 2.50 pt	
Subheaders: 6.00 pt	Drug Facts (continued): 8.00 pt	Hairlines: 0.50 pt	Average Kerning: 0

**McNeil** Submission Artwork

(b) (4)

**Active ingredient (in each caplet)**  
 ibuprofen 200 mg (NSAID)  
 '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. **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 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 or kidney disease, asthma, or had a stroke ■ 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

NDC 50580-110-38



**Motrin<sup>®</sup> IB**  
 ibuprofen Tablets USP, 200 mg  
 Pain Reliever/Fever Reducer (NSAID)



**300**  
 Coated Caplets\* Capsule-Shaped Tablets

doctor's care for any serious condition ■ 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 ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better ■ you have symptoms of heart problems or stroke: ■ chest pain ■ trouble breathing ■ weakness in one part or side of body ■ slurred speech ■ leg swelling ■ 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: ■ 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) ■ do not use if neck wrap or foil inner seal imprinted "SAFETY SEAL" is broken or missing

**Inactive ingredients** calcium stearate, colloidal silicon dioxide, FD&C yellow no. 6, hypromellose, iron oxide, magnesium stearate, modified starch, polydextrose, polyethylene glycol, pregelatinized starch, propylene glycol, shellac, stearic acid, titanium dioxide

**Questions or comments?** Call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)

Distributed by:  
**JOHNSON & JOHNSON CONSUMER INC.**  
 McNeil Consumer Healthcare Division  
 Fort Washington, PA 19034 USA  
 ©J&J 2017 [www.motrin.com](http://www.motrin.com)

Labeling Format Information: Fonts: HelveticaDF Cond Medium, Cond Bold, Cond Bold Italic			
Drug Facts: NA pt	Body Text: 6.00 pt	Bullets: 5.00 pt	Horizontal Scale: 79%
Headers: 7.00 pt	Leading: 6.50 pt	Barlines: NA pt	
Subheaders: 6.00 pt	Drug Facts (continued): NA pt	Hairlines: NA pt	Average Kerning: 0

**McNeil** Submission Artwork

(b) (4)

00000000



00000000



00000000

NDC 50580-110-38

# Motrin<sup>®</sup><sub>IB</sub>

## Ibuprofen Tablets USP, 200 mg

Pain Reliever /Fever Reducer (NSAID)

300 Coated Caplets\*



\*Capsule-Shaped Tablets

LOT:  
EXP:

3 0045-0481-375



00000000

NDC 50580-110-38

# Motrin<sup>®</sup><sub>IB</sub>

## Ibuprofen Tablets USP, 200 mg

Pain Reliever /Fever Reducer (NSAID)

300 Coated Caplets\*



\*Capsule-Shaped Tablets

**Drug Facts (continued)**

**Other information**

- store between 20-25°C (68-77°F)
- do not use if neck wrap or foil inner seal imprinted "SAFETY SEAL®" is broken or missing

**Inactive ingredients**

ca nauba wax, colloidal silicon dioxide, FD&C yellow no. 6, hypromellose, iron oxide, magnesium stearate, modified starch, polydextrose, polyethylene glycol, pregelatinized starch, propylene glycol, shellac, stearic acid, titanium dioxide

**Questions or comments?**

Call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)

Distributed by:  
**JOHNSON & JOHNSON CONSUMER INC.**  
McNeil Consumer Healthcare Division  
Fort Washington, PA 19034 USA  
©J&JCI 2017  
[www.motrin.com](http://www.motrin.com)

**Drug Facts (continued)**

- 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, kidney disease, asthma, or had a stroke
- 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 the 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

**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

**■ you have symptoms of heart problems or stroke:**

- chest pain
- weakness in one part or side of body
- slurred speech
- leg swelling
- 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	take 1 caplet every 4 to 6 hours while symptoms persist	ask a doctor
children under 12 years	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	

**Drug Facts**

**Active ingredient (in each caplet)**

ibuprofen 200 mg (NSAID)\*.....Pain reliever/fever reducer \*nonsteroidal anti-inflammatory drug

**Uses**

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - minor pain of arthritis
  - toothache
  - backache
  - 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
- asthma (wheezing)
- skin reddening
- shock
- facial swelling
- 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 including 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

**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 ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

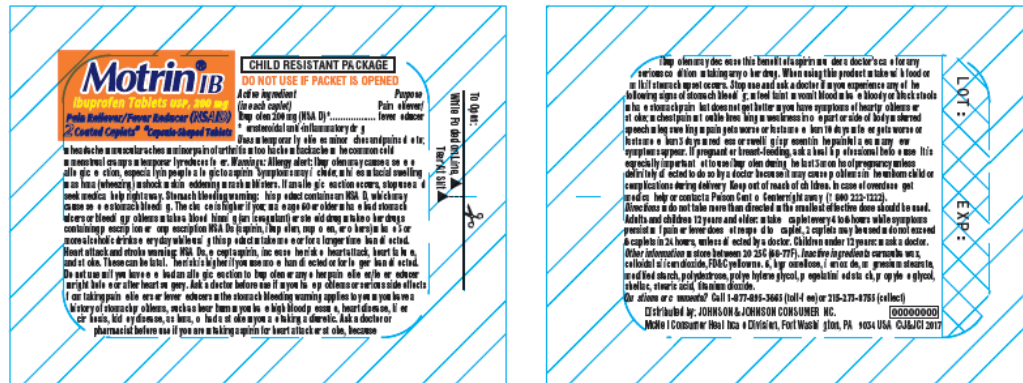
**Ask a doctor before use if**

- you have problems or serious side effects from taking pain relievers or fever reducers

**Labeling Format Information:** Fonts: HelveticaDF Cond Medium, Cond Bold, Cond Bold Italic

Drug Facts: 9.00 pt	Body Text: 6.00 pt	Bullets: 5.00 pt	Horizontal Scale: 90%
Headers: 8.00 pt	Leading: 6.50 pt	Barlines: 2.50 pt	
Subheaders: 6.00 pt	Drug Facts (continued): 8.00 pt	Hairlines: 0.50 pt	Average Kerning: 0

**McNeil** Submission Artwork



Labeling Format Information: Fonts: HelveticaDF Cond Bold, Cond Black, Cond Black Italic				
Drug Facts: NA pt	Body Text: 4.50 pt	Bullets: 3.50 pt	Horizontal Scale: 68%	
Headers: 4.50 pt	Leading: 4.50 pt	Barlines: NA pt	Average Kerning: -10	
Subheaders: 4.50 pt	Drug Facts (continued): NA pt	Hairlines: NA pt		



**Motrin<sup>IB</sup>**  
Ibuprofen Tablets USP, 200 mg

See New Warnings

NDC 50580-110-52

Coated Caplets

Convenient Take-Along Packs

Pain Reliever / Fever Reducer

See New Warnings

NDC 50580-110-52

**Motrin<sup>IB</sup>**  
Ibuprofen Tablets USP, 200 mg

Pain Reliever / Fever Reducer (NSAID)

Convenient Take-Along Packs

Coated Caplets

See New Warnings

NDC 50580-110-52

**Motrin<sup>IB</sup>**  
Ibuprofen Tablets USP, 200 mg

Pain Reliever / Fever Reducer (NSAID)

Convenient Take-Along Packs

Coated Caplets

50 Pouches of 2 Coated Caplets\* Each  
Total 100 Coated Caplets\*

Capsule-Shaped Tablets

**Drug Facts**

**Active ingredient (in each caplet)**  
Ibuprofen 200 mg (NSAID)\*  
\*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 thinner (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

**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 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 or kidney disease, asthma, or had a stroke
- 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

**Drug Facts (continued)**

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
- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness in one part or side of body
  - slurred speech
  - leg swelling
- 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	take 1 caplet every 4 to 6 hours while symptoms persist
children under 12 years	ask a doctor

**Other information**

- store between 20-25°C (68-77°F)
- do not use if packet is opened

**Inactive ingredients**  
ca nauba wax, colloidal silicon dioxide, FD&C yellow no. 6, hypromellose, iron oxide, magnesium stearate, modified starch, polydextrose, polyethylene glycol, pregelatinized starch, propylene glycol, stearic acid, titanium dioxide

**Questions or comments?**  
Call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)

Distributed by:  
JOHNSON & JOHNSON CONSUMER INC.  
McNeil Consumer Healthcare Division  
Fort Washington, PA 19004 USA  
©J&JCI 2017    www.motrin.com

**Labeling Format Information:** Fonts: HelveticaDF Cond Medium, Cond Bold, Cond Bold Italic

Drug Facts: 8.5 pt	Body Text: 6 pt	Bullets: 5.00 pt	Horizontal Scale: 90%
Headers: 8 pt	Leading: 6.5 pt	Barlines: 2.50 pt	
Subheaders: 6 pt	Drug Facts (colined): 8 pt	Halfines: 0.50 pt	Average Kerning: 0

**McNeil** Submission Artwork

**Active ingredient (in each caplet)** Purpose  
 Ibuprofen 200 mg (NSAID)..... Pain reliever/fever reducer  
 \*nonsteroidal anti-inflammatory drug

**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  
**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 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, kidney disease, asthma, or had a stroke ■ you are taking a diuretic

**For Hospital and Government Use Only**



NDC 50580-110-51

# Motrin<sup>®</sup> IB

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

Motrin IB

**500**  
**Coated Caplets\***

\*Capsule-Shaped Tablets

**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

**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 ■ you have symptoms of heart problems or stroke: ■ chest pain ■ trouble breathing ■ weakness in one part or side of body ■ slurred speech ■ leg swelling ■ 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:** ■ 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)  
 ■ do not use if neck wrap or foil inner seal imprinted "Safety Seal" is broken or missing

**Inactive ingredients**  
 carnauba wax, coloidal silicon dioxide, FD&C yellow no. 6, hypromellose, iron oxide, magnesium stearate, modified starch, polydextrose, polyethylene glycol, pregelatinized starch, propylene glycol, shellac, stearic acid, titanium dioxide

**Questions or comments?**  
 Call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)  
 Distributed by: **JOHNSON & JOHNSON CONSUMER INC.**  
 McNeil Consumer Healthcare Division  
 Fort Washington, PA 19034 USA ©J&JCI 2017

**Labeling Format Information:** Fonts: McNeil Cond Medium, Bold, Bold Italic

Drug Facts: NA pt	Body Text: 5.00 pt	Bullets: 4.00 pt	Horizontal Scale: 75%
Headers: 6.00 pt	Leading: 5.50 pt	Barlines: NA pt	
Subheaders: 5.00 pt	Drug Facts (continued): NA pt	Hairlines: NA pt	Average Tracking: 0

**McNeil** Submission Artwork

(b) (4)

0000000



**Drug Facts**

**Active ingredient (in each caplet)** Purpose  
Ibuprofen 200 mg (NSAID)\*.....Pain reliever/fever reducer  
\*nonsteroidal anti-inflammatory drug

**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
- asthma (wheezing)
- skin redness
- facial swelling
- shock
- 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

**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 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, kidney disease, asthma, or had a stroke
- 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

**For Hospital and Government Use Only**

See New Warnings

NDC 50580-110-51

# Motrin<sup>®</sup> IB

**Ibuprofen Tablets USP, 200 mg**

**Pain Reliever / Fever Reducer (NSAID)**

**500 Coated Caplets\***



\*Capsule-Shaped Tablets

0000000

EXP:  
LOT:



**For Hospital and Government Use Only**

See New Warnings

NDC 50580-110-51

# Motrin<sup>®</sup> IB

**Ibuprofen Tablets USP, 200 mg**

**Pain Reliever / Fever Reducer (NSAID)**

**500 Coated Caplets\***



\*Capsule-Shaped Tablets

**Motrin<sup>®</sup> IB**

**Ibuprofen Tablets USP, 200 mg**

**Pain Reliever / Fever Reducer (NSAID)**

**500 Coated Caplets\* \*Capsule-Shaped Tablets**

Distributed by:  
**JOHNSON & JOHNSON CONSUMER INC.**  
McNeil Consumer Healthcare Division  
Fort Washington, PA 19034 USA  
©J&JCI 2017

**Drug Facts (continued)**

**When using this product**

- take with food or milk if stomach upset occurs
- 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
- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness in one part or side of body
  - slurred speech
  - leg swelling
- 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**

- 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)
- do not use if neck wrap or foil inner seal imprinted "Safety Seal®" is broken or missing

**Inactive ingredients** carnauba wax, colloidal silicon dioxide FD&C yellow no. 6, hypromellose, iron oxide, magnesium stearate, modified starch, polydextrose, polyethylene glycol, pregelatinized starch, propylene glycol, shellac, stearic acid, titanium dioxide

**Questions or comments?**  
Call 1-877-895-3665 (toll-free) or 215-275-8755 (collect)



0000000

**Labeling Format Information:** Fonts: McNeil DF Med, Bold, Bold Italic

Drug Facts: 9.00 pt	Body Text: 6.00 pt	Bullets: 5.00 pt	Horizontal Scale: 100%
Headers: 8.00 pt	Leading: 6.50 pt	Barlines: 2.50 pt	
Subheaders: 6.00 pt	Drug Facts (continued): 8.00 pt	Hairlines: 0.50 pt	Average Tracking: 0

**McNeil** Submission Artwork

---

**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

---

/s/

---

KAREN M MAHONEY  
03/16/2017