

IBUPROFEN- ibuprofen capsule, liquid filled
Chain Drug Marketing Association Inc.

Ibuprofen Capsules (Liquid Filled), 200 mg

Active ingredient (in each capsule)

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)** (present as the free acid and potassium salt)

**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 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 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, asthma, or had a stroke
- 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

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.

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**
- adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 capsule, 2 capsules may be used
- do not exceed 6 capsules in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- each capsule contains: **potassium 20 mg**
- read all warnings and directions before use. Keep carton.
- store at 20°-25°C (68°-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

gelatin, medium-chain triglycerides, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution, and white ink

Questions or comments ?

Call toll free: **248-449-9300**

PRINCIPAL DISPLAY PANEL - 40ct

Ibuprofen Capsules, 200 mg

Pain Reliever/Fever Reducer (NSAID)

40 Liquid Filled Capsules

NDC 63868-281-40

The image displays the principal display panel of an Ibuprofen capsule box and two callout boxes. The box is white with a red top and bottom border. It features the 'QC QUALITY CHOICE' logo, the product name 'Ibuprofen', and 'Liquid Filled Softgels'. The text on the box includes 'Ibuprofen Capsules, 200 mg Pain Reliever/Fever Reducer (NSAID)', '40 Softgels', and 'Liquid Filled Capsules'. A circular inset shows a yellow and white capsule. The NDC number 'NDC 63868-281-40' is printed in the top right corner. A comparison claim states: '*Compare to the active ingredient in Motrin® IB Liquid Gels'. A barcode is located on the right side of the box, with the number '6 35515-99614 4' below it. A 'COATING FREE AREA' is indicated on the right edge. The bottom right corner contains fields for 'Lot No.' and 'Exp. Date.'. Two callout boxes are positioned above the box. The left callout box contains 'Drug Facts (continued)' with sections for 'Directions' and 'Other information'. The right callout box contains 'Drug Facts (continued)' with sections for 'Inactive ingredients' and 'Questions or comments?'. A '100% SATISFACTION GUARANTEED' logo is also present between the callout boxes.

Drug Facts (continued)
 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
 • adults and children 12 years and over:
 take 1 capsule every 4 to 6 hours while symptoms persist
 • if pain or fever does not respond to 1 capsule, 2 capsules may be used
 • do not exceed 6 capsules in 24 hours, unless directed by a doctor
 • children under 12 years: ask a doctor

Other information
 • each capsule contains: **potassium 20 mg**
 • read all warnings and directions before use. Keep carton.

Drug Facts (continued)
 • store at 20°-25°C (68°-77°F)
 • avoid excessive heat above 40°C (104°F)

Inactive ingredients gelatin, medium-chain triglycerides, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution and white ink

Questions or comments? Call toll free: 248-449-9300

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division, owner of the registered trademark Motrin® IB.

Distributed by C.D.M.A., Inc.®
 43157 W 9 Mile Rd
 Novi, MI 48375
 www.qualitychoice.com
 Questions: 248-449-9300

Made in China
 CDMA16-01

QC QUALITY CHOICE

Ibuprofen
 Liquid Filled Softgels
 Ibuprofen Capsules, 200 mg
 Pain Reliever/Fever Reducer (NSAID)

Ibuprofen
 Liquid Filled Softgels
 Ibuprofen Capsules, 200 mg
 Pain Reliever/Fever Reducer (NSAID)

40 Softgels¹ Liquid Filled Capsules

*Compare to the active ingredient in Motrin® IB Liquid Gels

NDC 63868-281-40

Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

6 35515-99614 4

COATING FREE AREA

Lot No:
 Exp. Date:

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts

Active ingredient (in each capsule) Purpose

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)**Pain reliever/Fever reducer (present as the free acid and potassium salt)
**nonsteroidal anti-inflammatory drug

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.

Drug Facts (continued)

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.

Drug Facts (continued)

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, asthma, or had a stroke
- 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

Drug Facts (continued)

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
 - leg swelling
 - weakness in one part or side of body
 - slurred speech
- 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.

NDC 63868-281-40



Ibuprofen

Liquid Filled Softgels

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

40 Softgels[†] Liquid Filled Capsules

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

Uses temporarily relieves minor aches and pains due to: headache, muscular aches, menstrual cramps, the common cold, backache, toothache, minor pain of arthritis.

Warnings

Ask your doctor before use if you are pregnant, under a doctor's care for a serious condition, age 60 or over, taking any other drug or have stomach problems.

This product 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.

Do not use this product if you have ever had an allergic reaction to any pain reliever/fever reducer.

Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (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

Drug Facts (continued under label)

Distributed by C.D.M.A., Inc.[®]
43157 W 9 Mile Rd
Novi, MI 48375
www.qualitychoice.com
Questions: 248-448-9300

Made in China
CDMA15-01

Lot No.:
Exp Date:



Reseal Area

■ 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.

Directions

- do not take more than directed
 - the smallest effective dose should be used
 - adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist
 - if pain or fever does not respond to 1 capsule, 2 capsules may be used
 - do not exceed 6 capsules in 24 hours, unless directed by a doctor
 - children under 12 years: ask a doctor
- Each capsule contains: potassium 20 mg**

Questions or comments?

call toll free: 248-449-9300

Hinge No Print or Text Area

PRINCIPAL DISPLAY PANEL - 80ct

Ibuprofen Capsules, 200 mg

Pain Reliever/Fever Reducer (NSAID)

80 Liquid Filled Capsules

NDC 63868-281-80

	<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> ■ do not take more than directed ■ the smallest effective dose should be used ■ adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 capsule, 2 capsules may be used ■ do not exceed 6 capsules in 24 hours, unless directed by a doctor ■ children under 12 years: ask a doctor <p>Other information</p> <ul style="list-style-type: none"> ■ each capsule contains: potassium 20 mg ■ read all warnings and directions before use. Keep carton. ■ store at 20°-25°C (68°-77°F) ■ avoid excessive heat above 40°C (104°F) <p>Inactive ingredients: gelatin, medium-chain triglycerides, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution and white ink</p>	<p>Drug Facts (continued)</p> <p>Questions or comments? Call toll free: 248-449-9300</p> <p>*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division, owner of the registered trademark Motrin® IB.</p> <p>100% SATISFACTION GUARANTEED</p> <p>Distributed by: C.D.M.A., Inc.® 43157 W 9 Mile Rd Novi, MI 48375 www.queiqualitychoice.com Questions: 248-449-9300</p> <p>Made in China CDMA18-01</p>	
<p>QC QUALITY CHOICE</p> <h1>Ibuprofen</h1> <p>Liquid Filled Softgels</p> <p>Ibuprofen Capsules, 200 mg Pain Reliever/Fever Reducer (NSAID)</p>	<p>NDC 63868-281-80</p> <p>QC QUALITY CHOICE</p> <p>*Compare to the active ingredient in Motrin® IB Liquid Gels</p> <h1>Ibuprofen</h1> <p>Liquid Filled Softgels</p> <p>Ibuprofen Capsules, 200 mg Pain Reliever/Fever Reducer (NSAID)</p>  <p>80 Softgels* Liquid Filled Capsules</p>	<p>Do Not Use If seal under bottle cap imprinted with "SEALED FOR YOUR PROTECTION" is broken or missing.</p>  <p>6 35515 99615 1</p> <p>COATING FREE AREA</p> <p>Lot No.: _____ Exp Date: _____</p>	

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts

Active ingredient (in each capsule)

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)**.....Pain reliever/Fever reducer (present as the free acid and potassium salt)
**nonsteroidal anti-inflammatory drug

Purpose

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.

Drug Facts (continued)

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.

Drug Facts (continued)

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, asthma, or had a stroke
- 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

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
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- 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.

NDC 63868-281-80



Ibuprofen

Liquid Filled Softgels

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

80 Softgels Liquid Filled Capsules

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Do Not Use if seal under bottle cap is imprinted with "SEALED FOR YOUR PROTECTION" is broken or missing.

- Uses**
- temporarily relieves minor aches and pains due to: headache, muscle aches, menstrual cramps, the common cold, backache, toothache, minor pain of arthritis.
 - temporarily reduces fever
- Warnings**
- Ask your doctor before use if you are pregnant, under a doctor's care for a serious condition, age 60 or over, taking any other drug or have stomach problems.
 - This product 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.
 - Do not use this product if you have ever had an allergic reaction to any pain reliever/fever reducer.
 - Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (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.

Drug Facts (continued under label)

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Lot No.:
Exp Date:

PEEL HERE

Reseal Area

Directions

- do not take more than directed
 - the smallest effective dose should be used
 - adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist
 - if pain or fever does not respond to 1 capsule, 2 capsules may be used
 - do not exceed 6 capsules in 24 hours, unless directed by a doctor
 - children under 12 years: ask a doctor
 - Each capsule contains: potassium 20 mg
- Questions or comments?** call toll free: 248-449-9300

Hinge

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-281
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
GELATIN (UNII: 2G86QN327L)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	green (Clear)	Score	no score
Shape	CAPSULE (Oblong)	Size	18mm
Flavor		Imprint Code	PC16
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-281-40	1 in 1 CARTON	07/13/2017	

1		40 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:63868-281-80	1 in 1 CARTON	07/13/2017	
2		80 in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA206568	07/13/2017		

Labeler - Chain Drug Marketing Association Inc. (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(63868-281) , analysis(63868-281)

Revised: 12/2019

Chain Drug Marketing Association Inc.