

MOTRIN IB- ibuprofen tablet, film coated

Morning Star OTC

Motrin IB

Drug Facts

Active ingredient (in each caplet)

Ibuprofen 200 mg (NSAID) ¹

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

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

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 at 20 weeks or later in 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 style="list-style-type: none"> ▪ 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 | <ul style="list-style-type: none"> ▪ ask a doctor |

Other information

- read all warnings and directions before use
- store between 20-25°C (68-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)

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

Repackaged by:

Morning Star OTC

145 S. Anderson St, Los Angeles,

CA 90033

PRINCIPAL DISPLAY PANEL-2 Tablets

| |
|---|
| Drug Facts (continued) |
| 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 <ul style="list-style-type: none">do not take more than directedthe smallest effective dose should be used adults and children 12 years and older <ul style="list-style-type: none">take 1 caplet every 4 to 6 hours while symptoms persistif pain or fever does not respond to 1 caplet, 2 caplets may be useddo 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 <ul style="list-style-type: none">read all warnings and directions before usestore between 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 |

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McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA
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www.motrin.com www.jjcpats.com

This product is repackaged by: Morning Star OTC
145 S. Anderson St., Los Angeles, CA 90033
Hours of operation 9 am - 4 pm, 323.354.4838



LOT
EXP

DO NOT USE IF INNER POUCH OR CARTON IS OPEN OR DAMAGED!

| Drug Facts | |
|--|-----------------------------|
| Active ingredient (in each caplet) | Purposes |
| Ibuprofen 200 mg (NSAID)* | Pain Reliever/fever reducer |
| *nonsteroidal anti-inflammatory drug | |
| Uses | |
| <ul style="list-style-type: none">temporarily relieves minor aches and pains due to:<ul style="list-style-type: none">headachemuscular achesminor pain of arthritistoothachebackachethe common coldmenstrual crampstemporarily reduces fever | |
| Warnings | |
| <p>Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:</p> <ul style="list-style-type: none">hivesfacial swellingasthma (wheezing)shockskin reddeningrashblisters <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chances are higher if you:</p> <ul style="list-style-type: none">are age 60 or olderhave had stomach ulcers or bleeding problemstake a blood thinning (anticoagulant) or steroid drugtake other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)have 3 or more alcoholic drinks every day while using this producttake more or for a longer time than directed <p>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.</p> | |

LEFT PANEL FOR CONTINUED DRUG FACTS

PRINCIPAL DISPLAY PANEL-2 Tablets x 25 Pouches



Drug Facts

Active ingredient (in each caplet) **Purposes**
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
 - backache
 - the common cold
 - menstrual cramps
 - temporarily reduces fever

Warnings

Caution: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- swelling of the face, lips, tongue, or throat
- difficulty breathing
- skin rash
- fever

Directions

Do not take more than directed

Other information

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)

Do not use

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:
 - black stool
 - blood in stool
 - dark, bloody or black stools
- you have stomach pain that does not get better

Drug Facts (continued)

■ you have symptoms of heart problems or stroke:

- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- trouble swallowing

■ pain gets worse or lasts more than 10 days

■ heart gets worse or lasts more than 10 days

■ redness or swelling is present in the painful area

■ any new symptoms appear

■ pregnant or breastfeeding, ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in pregnancy unless otherwise 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

- read all warnings and directions before use
- store between 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 1-800-774-7676 (collect) or visit www.motrin.com

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Richard Cookman Healthcare Division
Fort Washington, PA 19034 USA
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NLS 3051_0804705_001

Motrin[®] IB
Ibuprofen Tablets USP 200 mg
Pain Reliever / Fever Reducer (NSAID)

Convenient Take-Along Packs

Coated Caplets™

This product is repackaged by:
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145 S. Anderson St., Los Angeles, CA 90033
Hours of operation 9 am - 4 pm, 323.354.4838

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Motrin[®] IB
Ibuprofen Tablets USP 200 mg
Pain Reliever / Fever Reducer (NSAID)

Convenient Take-Along Packs

Coated Caplets™

25 Pouches of 2 Caplets each

Motrin[®] IB
Ibuprofen Tablets USP 200 mg
Pain Reliever / Fever Reducer (NSAID)

Convenient Take-Along Packs

Coated Caplets™

Actual Size of Pouch

MOTRIN IB

ibuprofen tablet, film coated

| Product Information | | | |
|-------------------------|----------------|--------------------|-------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53209-2001(NDC:50580-230) |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | |
|--|--|----------|
| Ingredient Name | | Strength |
| IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) | | 200 mg |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| ALUMINUM OXIDE (UNII: LMI26O6933) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |

| | | | | |
|--|---|--|-----------------------------|---------------------------|
| FERRIC OXIDE RED (UNII: 1K09F3G675) | | | | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | | | | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | | | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | | | | |
| | | | | |
| Product Characteristics | | | | |
| Color | orange | Score | no score | |
| Shape | OVAL | Size | 16mm | |
| Flavor | | Imprint Code | MOT | |
| Contains | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:53209-2001-2 | 25 in 1 POUCH | 06/19/2025 | |
| 1 | NDC:53209-2001-1 | 2 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| ANDA | ANDA077349 | | 06/19/2025 | |

Labeler - Morning Star OTC (078589357)

Registrant - Morning Star OTC (078589357)

| Establishment | | | |
|------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| Morning Star OTC | | 078589357 | repack(53209-2001) |

Revised: 6/2025

Morning Star OTC