

IBUPROFEN- ibuprofen capsule, liquid filled

P & L Development, LLC

Drug Facts

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

Ask a doctor before use if

- the 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
 - slurred speech
 - leg swelling
 - trouble breathing
 - weakness in one part or side of body
- 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 (1-800-222-1222) 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° to 25°C (68°to 77°F)
- avoid excessive heat above 40°C (104°F)
- swallow whole; do not crush, chew, or dissolve

Inactive ingredients

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

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

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

Ibuprofen

solubilized ibuprofen capsules, 200 mg

liquid filled softgels

pain reliever/ fever reducer (**NSAID**)*

softgels**

(**liquid filled capsules)

†This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division, distributor of Motrin® IB Liquid Gels.

TAMPER-EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590


Product Label

FD-092293 Lot No.: Exp. Date:

PLD-45278

3 59726 74920 6

PL Developments
200 Hicks Street
Westbury, NY 11590




Compare to the active ingredient in Motrin® IB Liquid Gels¹
NDC 59726-279-20

Ibuprofen

solubilized ibuprofen capsules, 200 mg

liquid filled softgels
pain reliever/
fever reducer **(NSAID)**

20 softgels**
(*liquid filled capsules)



Drug Facts

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 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

Drug Facts (continued)

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 you have the 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:

Drug Facts (continued)

chest pain slurred speech leg swelling
trouble breathing weakness in one part or side of body 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 (1-800-222-1222) right away.

Directions do not take more than directed
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adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist
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Other information each capsule contains: potassium 20 mg read all warnings and directions before use. Keep carton. Store at 20° to 25°C (68° to 77°F) avoid excessive heat above 40°C (104°F)

Drug Facts (continued)

swallow whole; do not crush, chew, or dissolve

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

Questions or comments?
Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

READYinCASE Ibuprofen 200 mg Clear Softgels

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:59726-279

| | |
|--------------------------------|------|
| Route of Administration | ORAL |
|--------------------------------|------|

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM) | IBUPROFEN | 200 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| GELATIN (UNII: 2G86QN327L) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POTASSIUM HYDROXIDE (UNII: WZH3C48M4T) | |
| WATER (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |
| SORBITAN (UNII: 6O92ICV9RU) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |

Product Characteristics

| | | | |
|-----------------|----------------|---------------------|----------|
| Color | yellow (Clear) | Score | no score |
| Shape | CAPSULE | Size | 18mm |
| Flavor | | Imprint Code | P24 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:59726-279-20 | 1 in 1 BOX | 12/01/2024 | |
| 1 | | 20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA206568 | 12/01/2024 | |

Labeler - P & L Development, LLC (800014821)

Revised: 10/2024

P & L Development, LLC