

IBUPROFEN - ibuprofen capsule
RITE AID CORPORATION

Ibuprofen Capsules

Drug Facts

Active ingredient (in each capsule)

Solubilized ibuprofen equal to 200 mg ibuprofen USP (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
 - muscular aches
 - the common cold
 - 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 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)

Inactive ingredients

FD & C green no. 3, gelatin (bovine), polyethylene glycol, potassium hydroxide, purified water and sorbitol sorbitan solution.

Questions or comments?

call **1-855-274-4122**

DISTRIBUTED BY: RITE AID,
30 HUNTER LANE, CAMP HILL,
PA 17011
www.riteaid.com

MADE IN INDIA

Code: TS/DRUGS/16/2014

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 200 mg (20 Capsules Bottle)

NDC 11822-4258-1

PAIN RELIEF

IBUPROFEN

CAPSULES, 200 mg

PAIN RELIEVER/FEVER REDUCER

(NSAID)

**READ AND KEEP CARTON FOR COMPLETE
WARNINGS AND INFORMATION.**

20
LIQUID FILLED CAPSULES

Top Ply

| | | | | | |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|----------------------------------|
| | <p>NDC 11822-4258-1</p> <p>PAIN RELIEF</p> <p>IBUPROFEN</p> <p>CAPSULES, 200 mg</p> <p>PAIN RELIEVER/FEVER REDUCER (NSAID)</p> <p>20 LIQUID FILLED CAPSULES</p> <p>READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION.</p> | <p>Do not use if seal imprinted with SEALED for YOUR PROTECTION under the bottle cap is broken or missing.</p> <p>DISTRIBUTED BY: RITE AID, 30 HUNTER LANE, CAMP HILL, PA 17011 www.riteaid.com MADE IN INDIA</p> <p>SATISFACTION GUARANTEE: If you're not satisfied, we'll happily refund your money. Code: TS/DRUGS/16/2014</p> | <p>Active ingredient (in each capsule) Solubilized ibuprofen equal to 200 mg.....Pain reliever/fever reducer ibuprofen USP (NSAID)* (present as the free acid and potassium salt) *nonsteroidal anti-inflammatory drug</p> <p>Uses ■ temporarily relieves minor aches and pains due to: ■ headache ■ toothache ■ backache ■ menstrual cramps ■ muscular aches ■ the common cold ■ minor pain of arthritis ■ temporarily reduces fever</p> | <p>Purpose Pain reliever/fever reducer</p> <p>LM-4916 P1430438</p> | <p>Litigation for Drug Facts</p> |
| | <p>No Varnish</p> | | | | |

Top Ply (Page #1)

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| <p>Warnings</p> <p>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.</p> | <p>LM-4916 P1430438</p> |
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Back of Top Ply (Page #2)

Bottom Ply

Base (Page #3)

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| <p>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 (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). Inactive ingredients FD & C green no. 3, gelatin (bovine), polyethylene glycol, potassium hydroxide, purified water and sorbitol sorbitan solution. Questions or comments? call 1-866-274-4122</p> | <p>LM-4916 P1430438</p> |
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PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 200 mg (20 Capsules Container Carton)

FREE FROM GLUTEN FREE PARABEN FREE

Compare to the active ingredient in Advil® Liqui-Gels®†

NDC 11822-4258-1

PAIN RELIEF

**IBUPROFEN
CAPSULES, 200 mg
PAIN RELIEVER/FEVER REDUCER
(NSAID)**

**ACTUAL SIZE
1200**

**READ AND KEEP CARTON FOR COMPLETE
WARNINGS AND INFORMATION.**

**20
LIQUID FILLED CAPSULES**



Drug Facts (continued)

- 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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- 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)

- Inactive ingredients**
- FD & C green no. 3, gelatin (bovine), polyethylene glycol, potassium hydroxide, purified water and sorbitol sorbitan solution.

Questions or comments?
call 1-855-274-4122

Compare to the active ingredient in Advil® Liquid-Gels™
NDC 11822-42031-1

**PAIN RELIEF
IBUPROFEN
CAPSULES, 200 mg
PAIN RELIEVER/FEVER REDUCER
(NSAID)**

ACTUAL SIZE
1200

20
LIQUID FILLED CAPSULES

FREE FROM PARABENS

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Do not use if seal imprinted with SEALED for YOUR PROTECTION under the bottle cap is broken or missing.

Drug Facts

Active ingredient (in each capsule) **Purpose**

Solubilized ibuprofen equal to 200 mg ibuprofen USP (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
• muscular aches • the common cold • 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

*This product is not manufactured or distributed by GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDINGS US LLC, distributor of Advil® Liquid-Gels®.

Drug Facts (continued)

- 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

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www.riteaid.com
MADE IN INDIA

Satisfaction Guarantee: If you're not satisfied, we'll happily refund your money.
Code: TS/DRUGS/16/2014



LOT:
EXP:

IBUPROFEN

ibuprofen capsule

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11822-4258 |
| 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 |
|---------------------------------------------------|-----------------|
| FD&C GREEN NO. 3 (UNII: 3P3ONR601S) | |
| GELATIN, UNSPECIFIED (UNII: 2G86QN327L) | |
| POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9) | |
| POTASSIUM HYDROXIDE (UNII: WZH3C48M4T) | |
| WATER (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |
| 1,4-SORBITAN (UNII: AV0YTZ4E6J) | |
| MANNITOL (UNII: 3OWL53L36A) | |

Product Characteristics

| | | | |
|-----------------|--------------------|---------------------|----------|
| Color | GREEN | Score | no score |
| Shape | RECTANGLE (Oblong) | Size | 19mm |
| Flavor | | Imprint Code | I200 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|----------------------------------------------------|-----------------------------|---------------------------|
| 1 | NDC:11822-4258-1 | 1 in 1 CARTON | 06/24/2022 | |
| 1 | | 20 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:11822-4258-2 | 1 in 1 CARTON | 06/24/2022 | |
| 2 | | 40 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 3 | NDC:11822-4258-3 | 1 in 1 CARTON | 06/24/2022 | |
| 3 | | 80 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 4 | NDC:11822-4258-4 | 160 in 1 BOTTLE; Type 0: Not a Combination Product | 06/24/2022 | |

| 5 | NDC:11822-4258-5 | 300 in 1 BOTTLE; Type 0: Not a Combination Product | 06/24/2022 | |
|------------------------------|------------------------------------------|-------------------------------------------------------------|--------------------|--|
| 6 | NDC:11822-4258-6 | 200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/12/2023 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| ANDA | ANDA207753 | 06/24/2022 | | |

Labeler - RITE AID CORPORATION (014578892)

Registrant - Aurohealth LLC (078728447)

| Establishment | | | |
|------------------------|---------|-----------|------------------------------------------------|
| Name | Address | ID/FEI | Business Operations |
| APL HEALTHCARE LIMITED | | 650844777 | ANALYSIS(11822-4258) , MANUFACTURE(11822-4258) |

Revised: 4/2023

RITE AID CORPORATION