

DYE-FREE IBUPROFEN- ibuprofen capsule, liquid filled
RITE AID CORPORATION

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
- 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 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.

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.
- store at 20° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F). Protect from light.

Inactive ingredients

gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan and sorbitol

Questions or comments?

call toll free **1-888-235-2466**

†All trademarks are property of their respective owners. This product is not affiliated with the owners of Motrin[®] IB Liquid Gels.

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

SATISFACTION GUARANTEE:

**If you're not satisfied, we'll
happily refund your money.**

R0422

L0000634

120's Bottle Label

NDC 11822-1879-1

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

DYE FREE

IBUPROFEN

IBUPROFEN CAPSULES 200 mg

PAIN RELIEVER /

FEVER REDUCER

(NSAID)

ACTUAL SIZE

DO NOT USE IF TAMPER-EVIDENT

SEAL UNDER BOTTLE CAP

IMPRINTED WITH "SEALED for YOUR PROTECTION" IS BROKEN

OR MISSING.

120

LIQUID GELS**

(**LIQUID-FILLED CAPSULES)

NDC 11822-1879-1

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

DYE FREE
IBUPROFEN
IBUPROFEN CAPSULES 200 mg

PAIN RELIEVER/
FEVER REDUCER
(NSAID)

ACTUAL SIZE

DO NOT USE IF TAMPER-EVIDENT
SEAL UNDER BOTTLE CAP
IMPRINTED WITH "SEALED for
YOUR PROTECTION" IS BROKEN
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120
LIQUID GELS**
(*LIQUID FILLED CAPSULES)

Drug Facts

Active ingredient (in each capsule) Purpose
Sulfalized 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. Symptoms may include:
■ hives ■ facial swelling ■ asthma (wheezing) ■ shock
■ skin redness ■ 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

DISTRIBUTED BY: INVITE-AD,
30 HINTERLANE, CAMP HILL,
PA 17011. www.nxact.com
SATISFACTION GUARANTEE:
If you're not satisfied, we'll
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R0422

Lot No.: 0 11822 12988 6

PEEL HERE

Exp. Date:

| |
|---|
| Drug Facts (continued) |
| <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ take with food or milk if stomach upset occurs |
| Stop use and ask a doctor if <ul style="list-style-type: none"> ■ you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> ■ 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: <ul style="list-style-type: none"> ■ chest pain ■ trouble breathing ■ weakness in one part or side of body ■ slurred speech ■ leg swelling |
| <ul style="list-style-type: none"> ■ 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. |
| Directions <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 |
| Other information <ul style="list-style-type: none"> ■ each capsule contains: potassium 20 mg ■ read all warnings and directions before use ■ store at 20° to 25°C (68° to 77°F) ■ avoid excessive heat above 40°C (104°F). Protect from light. |
| Inactive ingredients <ul style="list-style-type: none"> gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan, and sorbitol |
| Questions or comments? call toll-free 1-888-235-2466 |

This product is not manufactured or distributed by the owners of Motrin® IB Liquid Gels.

DYE-FREE IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11822-1879 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) | IBUPROFEN | 200 mg in 120 |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| GELATIN, UNSPECIFIED (UNII: 2G86QN327L) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| WATER (UNII: 059QF0KO0R) | |
| POTASSIUM HYDROXIDE (UNII: WZ H3C48M4T) | |
| SORBITAN (UNII: 6O92ICV9RU) | |
| SORBITOL (UNII: 506T60A25R) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|----------|
| Color | white | Score | no score |
| Shape | CAPSULE | Size | 15mm |
| Flavor | | Imprint Code | IB5 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
| | | | | |

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|----------|------------------|--|------------|--|
| 1 | NDC:11822-1879-1 | 120 in 1 BOTTLE; Type 0: Not a Combination Product | 04/30/2021 | |
|----------|------------------|--|------------|--|

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA078682 | 04/30/2021 | |

Labeler - RITE AID CORPORATION (014578892)

Registrant - Bionpharma Inc. (079637826)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|-------------------------|
| Patheon Softgels Inc. | | 002193829 | manufacture(11822-1879) |

Revised: 12/2023

RITE AID CORPORATION