

IBUPROFEN- ibuprofen capsule, liquid filled
Dolgenercorp, Inc. (DOLLAR GENERAL & REXALL)

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
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - slurred speech
 - trouble breathing
 - leg swelling
 - 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 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 (1-800-222-1222).

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
- store at 20 to 25°C (68 to 77°F)
- avoid excessive heat above 40°C (104°F)
- read all warnings and directions before use. Keep carton.
- swallow whole, do not crush, chew, or dissolve

Inactive ingredients

FD&C blue #1, FD&C yellow#6, gelatin, lecithin (soybean), medium-chain triglycerides, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan, sorbitol

Questions or comments?

Call toll free **1-866-4-REXALL**

Principal Display Panel

Ibuprofen Softgels

Solubilized Ibuprofen Capsules, 200 mg

Pain Reliever/Fever Reducer **(NSAID)**

Softgels**

(**Liqui-Filled Capsules)

TAMPER EVIDENT: DO NOT USE IF SEAL UNDER BOTTLE CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION.

DISTRIBUTED BY: DOLGENCORP,LLC

100 MISSION RIDGE

GOODLETTSVILLE,TN 37072 USA

Product Label



Ibuprofen Softgels

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



Actual Size

40
Softgels**

**Liquid Filled Capsules

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Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Drug Facts (continued)

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Inactive ingredients

FD&C blue no. 1, FD&C yellow no. 6, gelatin, lecithin (soybean), medium-chain triglycerides, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan

Questions or comments?

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Visit us at: Rexall.com or call 1-866-4-REXALL

PACKAGED FOR DOLGENCORP, LLC
100 MISSION RIDGE, GOODLETTSVILLE, TN 37072 USA

Since 1903 Rexall® is a registered trademark of Rexall Sundown, Inc.

Lot No.:
Exp. Date:

P.L.D.-CS239A
FD005394



REXALL Ibuprofen 200 mg Softgels

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55910-651 |
| 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 BLUE NO. 1 (UNII: H3R47K3TBD) | |
| 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) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|----------|
| Color | green | Score | no score |
| Shape | CAPSULE | Size | 19mm |
| Flavor | | Imprint Code | AT146 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:55910-651-40 | 1 in 1 BOX | 09/30/2018 | 01/31/2025 |
| 1 | | 40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|------------------|--|------------------------|----------------------|
|------------------|--|------------------------|----------------------|

| Category | Citation | Date | Date |
|----------|------------|------------|------------|
| ANDA | ANDA206999 | 09/30/2018 | 01/31/2025 |

Labeler - Dolgencorp, Inc. (DOLLAR GENERAL & REXALL) (068331990)

Revised: 10/2022

Dolgencorp, Inc. (DOLLAR GENERAL & REXALL)