

IBUPROFEN - ibuprofen capsule
Aurohealth LLC

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, polyethylene glycol, potassium hydroxide, purified water and sorbitol sorbitan solution.

Questions or comments?

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

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road

East Windsor, NJ 08520

Made in India

Code No.: TS/DRUGS/16/2014

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 200 mg (40 Capsules Bottle)

AUROHEALTH

NDC 58602-843-12

Ibuprofen Capsules

200 mg

Pain Reliever/Fever Reducer (NSAID)

40 Liquid Filled


Capsules

I200

Actual Size

**READ ANDA KEEP CARTON FOR COMPLETE
WARNING AND INFORMATION**

Top Layer Printing side

| | | |
|--|--|--------------------------------|
|  <p>NDC 58602-843-12</p> <h1>Ibuprofen Capsules</h1> <h2>200 mg</h2> <p>Pain Reliever/Fever Reducer (NSAID)</p> <p>40 Liquid Filled Capsules</p> <p>READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION</p> | <p>Drug Facts</p> <p>Active ingredient (in each capsule) 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</p> <p>Purpose</p> | <p>Use Here for Drug Facts</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: AUROHEALTH LLC 279 Princeton-Hightstown Road * East Windsor, NJ 08520 Made in India Code: TS/DRUGS/16/2014</p> <p>P1429988</p> | |

Position for Vendor logo

* Lot: XXXXXXXXX
EXP: MM/YYYY
Prefix & Variables of Lot, EXP shall be printed online during packing.

Top Layer Adhesive side

| | | | |
|-----------------|--|---|--|
| <p>P1429988</p> | <p>Drug Facts (continued)</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>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</p> | <p>Drug Facts (continued)</p> <p>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.</p> <p>Do not use ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer ■ right before or after heart surgery.</p> <p>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.</p> <p>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</p> | <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Gluing Area</p> |
| | <p>Warnings ■ taking any other drug.</p> <p>When using this product ■ take with food or milk if stomach upset occurs</p> <p>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.</p> <p>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</p> | | |

Base Layer

| | | |
|--|---|-----------------|
| <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Gluing Area</p> | <p>Drug Facts (continued)</p> <p>or contact a Poison Control Center (1-800-222-1222) right away.</p> <p>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</p> <p>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)</p> <p>Inactive ingredients FD & C green no. 3, gelatin, polyethylene glycol, potassium hydroxide, purified water and sorbitol sorbitan solution.</p> <p>Questions or comments? call 1-855-274-4122</p> | <p>P1429988</p> |
| | <p>Drug Facts (continued)</p> <p>■ taking any other drug.</p> <p>When using this product ■ take with food or milk if stomach upset occurs</p> <p>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.</p> <p>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</p> | |

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 200 mg (40 Capsules Container Carton)

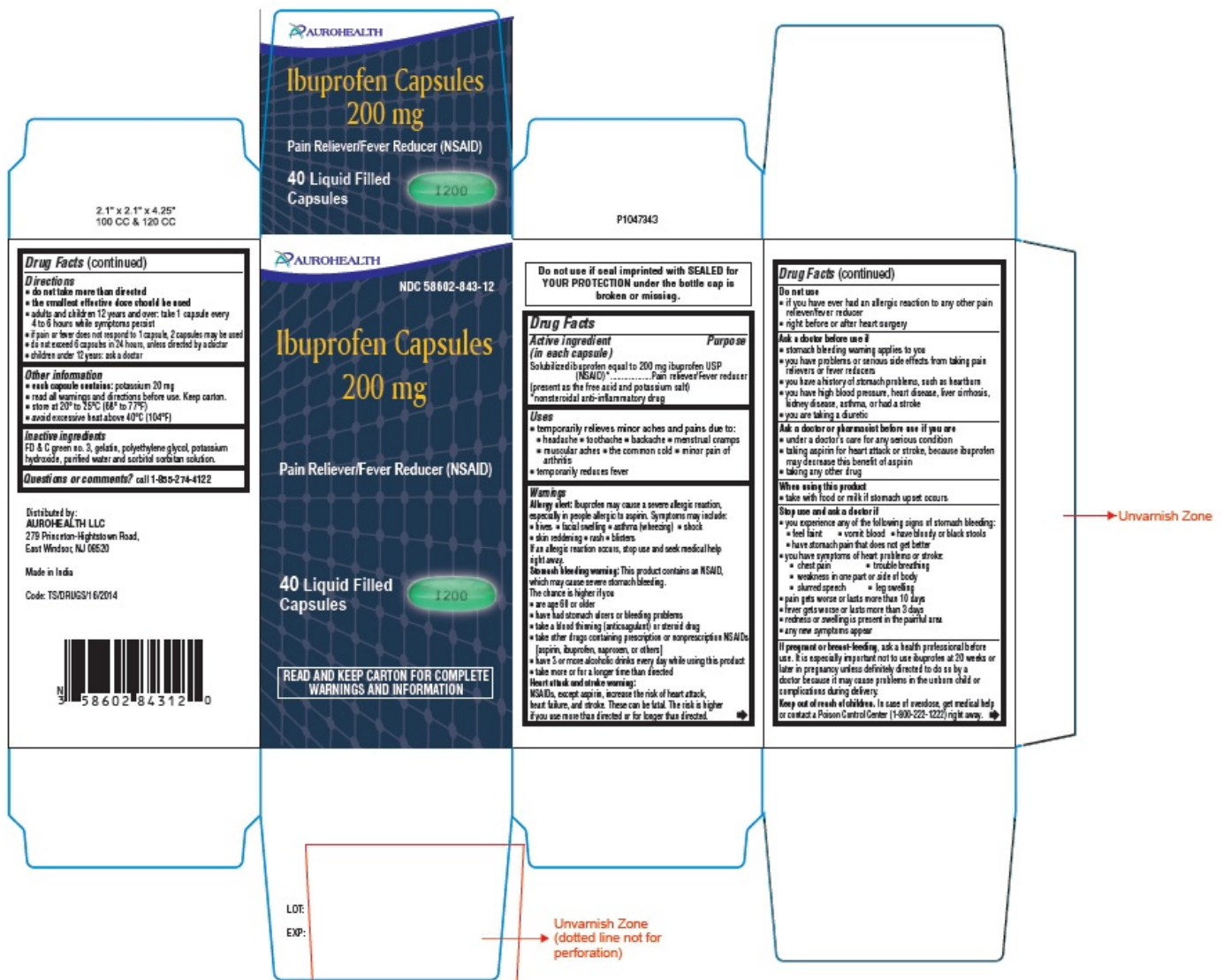
AUROHEALTH
NDC 58602-843-12
Ibuprofen Capsules
200 mg

Pain Reliever/Fever Reducer (NSAID)

40 Liquid Filled Capsules

1200
 Actual Size

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION



IBUPROFEN

ibuprofen capsule

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58602-843 |
| 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: 3P3ONR6O1S) | |
| GELATIN, UNSPECIFIED (UNII: 2G86QN327L) | |
| POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9) | |
| POTASSIUM HYDROXIDE (UNII: WZH3C48M4T) | |
| WATER (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |
| 1,4-SORBITAN (UNII: AV0Y TZ4E6J) | |
| 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:58602-843-73 | 1 in 1 CARTON | 07/15/2020 | |
| 1 | | 20 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:58602-843-12 | 1 in 1 CARTON | 07/15/2020 | |
| 2 | | 40 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 3 | NDC:58602-843-18 | 1 in 1 CARTON | 07/15/2020 | |
| 3 | | 80 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 4 | NDC:58602-843-30 | 160 in 1 BOTTLE; Type 0: Not a Combination Product | 07/15/2020 | |
| 5 | NDC:58602-843-38 | 300 in 1 BOTTLE; Type 0: Not a Combination Product | 07/15/2020 | |
| 6 | NDC:58602- | 180 in 1 BOTTLE; Type 0: Not a Combination | 07/15/2020 | |

| | | | | |
|----|------------------|---|------------|--|
| 6 | 843-32 | Product | 07/15/2020 | |
| 7 | NDC:58602-843-79 | 2 in 1 CARTON | 07/15/2020 | |
| 7 | | 180 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 8 | NDC:58602-843-70 | 1 in 1 CARTON | 08/27/2020 | |
| 8 | | 40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| 9 | NDC:58602-843-72 | 1 in 1 CARTON | 08/27/2020 | |
| 9 | | 80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| 10 | NDC:58602-843-74 | 160 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/27/2020 | |
| 11 | NDC:58602-843-92 | 180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/27/2020 | |
| 12 | NDC:58602-843-34 | 200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/27/2020 | |
| 13 | NDC:58602-843-75 | 300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/27/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA207753 | 07/15/2020 | |

Labeler - Aurohealth LLC (078728447)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|--|
| APL HEALTHCARE LIMITED | | 650844777 | ANALYSIS(58602-843) , MANUFACTURE(58602-843) |

Revised: 5/2022

Aurohealth LLC