

**IBUPROFEN MINIS - ibuprofen capsule, liquid filled**  
**Harris Teeter**

-----  
**Ibuprofen Capsules 200 mg (minis)**

***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
  - 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 (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 15 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** (Monday – Friday 8:30 AM to 5:00

PM EST)

**PROUDLY DISTRIBUTED BY:  
HARRIS TEETER, LLC  
MATTHEWS, NC 28105**

Made in India

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - Container Label 200 mg (80  
Liquid Filled Capsules)**

**Harris Teeter™**

**Ibuprofen  
Capsules 200 mg**

**PAIN RELIEVER/FEVER  
REDUCER (NSAID)**

**minis**

**80 Liquid Filled Capsules**



# Ibuprofen

Capsules 200 mg

PAIN RELIEVER/FEVER  
REDUCER (NSAID)

minis

80 Liquid Filled Capsules

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.

Lift Here  
for  
Drug Facts

 your *plus* guarantee.  
1-800-432-6111 or harristeeter.com

PROUDLY DISTRIBUTED BY:  
HARRIS TEETER, LLC  
MATTHEWS, NC 28105

Made in India

P 1 4 3 4 7 3 5 L M - 5 8 6 9

\*  
Unvarnished Zone  
(dotted line not for printing)  
44 x 15 mm

## Top Layer Adhesive side

P 1 4 3 4 7 3 5 L M - 5 8 6 9

### 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

### 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

### Purpose

Gluing Area

## Base Layer

Gluing Area

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 15 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 (Monday - Friday 8:30 AM to 5:00 PM EST)

P 1 4 3 4 7 3 5 L M - 5 8 6 9

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - Container Carton Label 200 mg  
(80 Liquid Filled Capsules)**

**Harris Teeter™**

†Compare to  
the active  
ingredient  
of Advil®  
LIQUI-GELS®

**Ibuprofen  
Capsules 200 mg**

**PAIN RELIEVER/FEVER REDUCER (NSAID)**

**Smaller Capsule  
Same Strength**

**minis**

**80 Liquid Filled Capsules**



## IBUPROFEN MINIS

ibuprofen capsule, liquid filled

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:72036-015 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength |
|---|-------------------|----------|
| <b>IBUPROFEN</b> (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM) | 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 SOLUTION (UNII: 8KW3E207O2)       |          |

**Product Characteristics**

|          |                     |              |          |
|----------|---------------------|--------------|----------|
| Color    | GREEN (transparent) | Score        | no score |
| Shape    | OVAL                | Size         | 12mm     |
| Flavor   |                     | Imprint Code | Q21      |
| Contains |                     |              |          |

**Packaging**

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:72036-015-80 | 1 in 1 CARTON                                     | 08/16/2024           |                    |
| 1 |                  | 80 in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |

**Marketing Information**

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA215777                               | 08/16/2024           |                    |

**Labeler** - Harris Teeter (047279351)

**Registrant** - Aurohealth LLC (078728447)

**Establishment**

| Name                   | Address | ID/FEI    | Business Operations                          |
|------------------------|---------|-----------|--|
| APL HEALTHCARE LIMITED |         | 650844777 | ANALYSIS(72036-015) , MANUFACTURE(72036-015) |