

IBUPROFEN MINIS - ibuprofen capsule, liquid filled
Aurohealth LLC

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)

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road

East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/16/2014

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

AUROHEALTH

NDC 58602-858-18

Ibuprofen Capsules

200 mg


(minis)

Pain Reliever/Fever Reducer (NSAID)

80

Liquid Filled Capsules

Top Layer Printing side



NDC 58602-858-18

Ibuprofen Capsules

200 mg (minis)

Pain Reliever/Fever Reducer (NSAID)

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

P 1 4 2 6 9 7 9

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Code: TS/DRUGS/16/2014

Position for Vendor logo

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

Top Layer Adhesive side

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

Use
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
Pain reliever/Fever reducer

P 1 4 2 6 9 7 9

Gluing Area

Base Layer

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.

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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 2 6 9 7 9

Gluing Area

Gluing Area

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

AUROHEALTH

NDC 58602-858-18

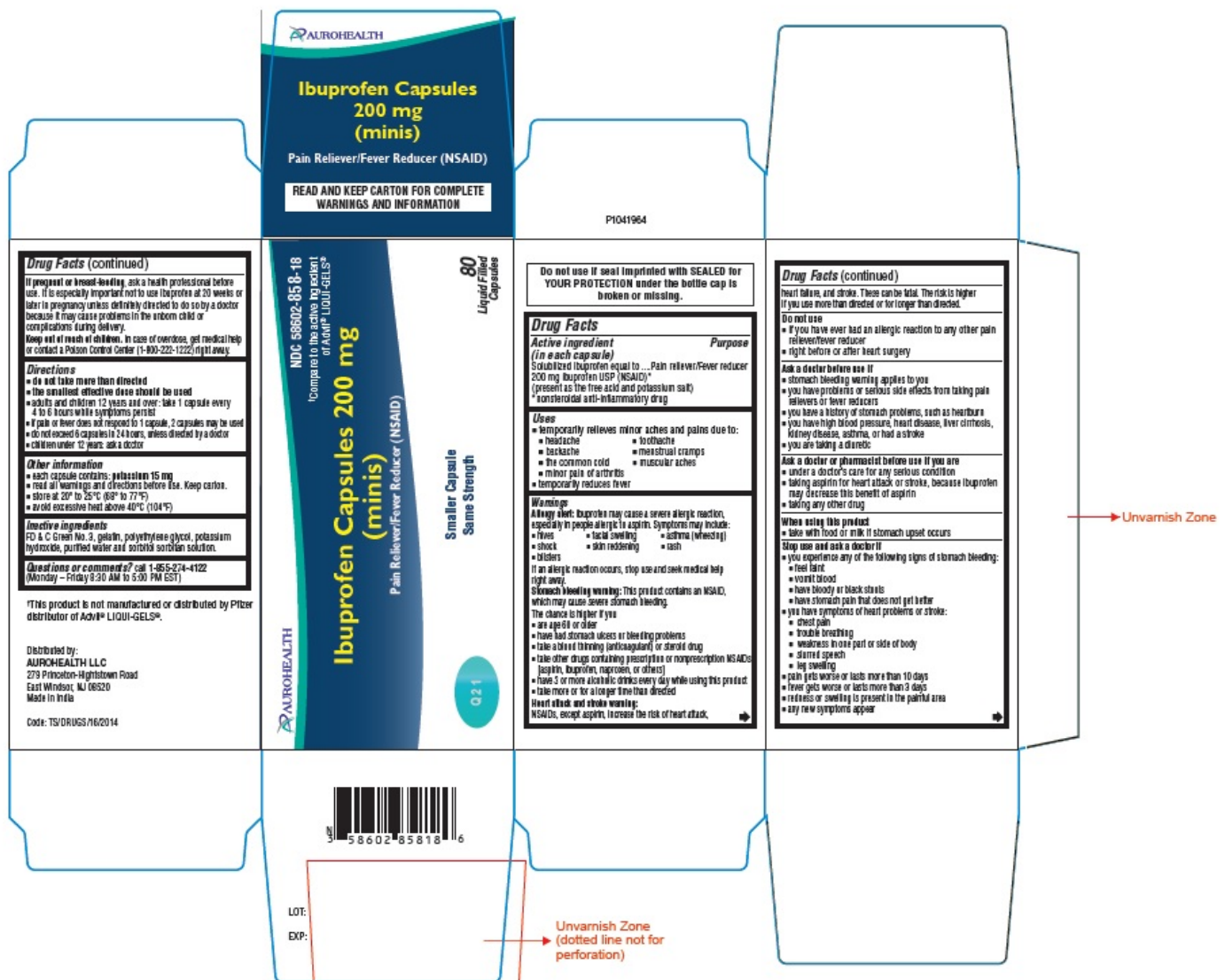
†Compare to the active Ingredient
of Advil LIQUI®-GELS®

Ibuprofen Capsules 200 mg
(minis)

Pain Reliever/Fever Reducer (NSAID)

Smaller Capsule
Same Strength

80
Liquid Filled
Capsules



IBUPROFEN MINIS

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-858
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 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:58602-858-73	1 in 1 CARTON	09/14/2023	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-858-12	1 in 1 CARTON	09/14/2023	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-858-18	1 in 1 CARTON	09/14/2023	
3		80 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-858-23	1 in 1 CARTON	09/14/2023	
4		120 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-858-30	160 in 1 BOTTLE; Type 0: Not a Combination Product	09/14/2023	
6	NDC:58602-858-34	200 in 1 BOTTLE; Type 0: Not a Combination Product	09/14/2023	

7	NDC:58602-858-42	240 in 1 BOTTLE; Type 0: Not a Combination Product	09/14/2023	
8	NDC:58602-858-96	1 in 1 CARTON	09/14/2023	
8		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
9	NDC:58602-858-70	1 in 1 CARTON	09/14/2023	
9		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
10	NDC:58602-858-72	1 in 1 CARTON	09/14/2023	
10		80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
11	NDC:58602-858-80	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/14/2023	
12	NDC:58602-858-98	240 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/14/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215777	09/14/2023	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-858) , MANUFACTURE(58602-858)

Revised: 9/2023

Aurohealth LLC