

IBUPROFEN- ibuprofen tablet, coated
PLD Acquisitions LLC DBA Avéma Pharma Solutions

DRUG FACTS

Active Ingredient (in each caplet)

Ibuprofen USP, 200 mg (NSAID)*

*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
- rash
- blisters
- skin reddening

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 blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

- take more or for a longer time than directed.
- have 3 or more alcoholic drinks every day while using this product

Do not use

- if you 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, or kidney disease
- you have asthma
- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed.

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
 - pain gets worse or last more than 10 days
 - fever gets worse or last 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 older:
 - take 1 caplet every 4 to 6 hours while symptoms persist
 - if pain or fever does not respond to 1 caplet, 2 caplets may be used
 - do not exceed 6 caplets in 24 hours, unless directed by a doctor
- children under 12 years : ask a doctor

Other information

- store between 20°- 25° C (68°- 77° F)

Inactive Ingredients

carnauba wax, croscarmellose sodium, FD&C yellow #6 aluminium lake, hypromellose, microcrystalline cellulose, polydextrose, polyethylene glycol, pregelatinized starch, silicon dioxide, stearic acid, titanium dioxide.

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Ibuprofen Tablets USP, 200 mg

Pain Reliever/ Fever Reducer (NSAID)

Coated Caplets**

**(Capsule-Shaped Tablets)

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

Manufactured by: Avema Pharma Solutions

10400 NW 29th Terrace

Miami, FL 33172

Product Label

Ibuprofen

1000 COATED CAPLETS**
**** (Capsule-Shaped Tablets)**

Drug Facts

Active ingredient (in each caplet)

Purpose

ibuprofen USP, 200 mg (NSAID)*.....Pain reliever/fever reducer
***nonsteroidal anti-inflammatory drug**

Uses

- temporarily relieves minor aches and pains due to:

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- temporarily relieves minor aches and pains due to:
 - headache
 - backache
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 - muscular aches
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 - minor pain of arthritis
 - menstrual cramps
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- hives
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- rash
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- shock

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- 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) ■ take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product

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

- 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, or kidney disease
- you have asthma ■ you are taking a diuretic

Drug Facts (continued under label)

Manufactured by: Avema Pharma Solutions
10400 NW 29th Terrace
Miami, FL 33172

160B
LB0004

Lot No.:

Exp. Date:

PEEL
HERE**Drug Facts** (continued)

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition

- taking any other drug

When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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9AM-5PM EST

Ibuprofen 200 mg orange Caplets

NO PRINT
NO VARNISH
NO COATING

NDC 63548-0185-2

Tablets USP, 200 mg
Pain Reliever/ Fever Reducer (NSAID)



100 COATED CAPLETS**
**** (Capsule-Shaped Tablets)**

- ▶ have had stomach ulcers or bleeding problems
- ▶ are age 60 or older
- ▶ 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

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
- 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

QUESTIONS OR COMMENTS:
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160B
FC000559
Lot No.:
Exp. Date:



3 59726 18510 3

Ibuprofen 200 mg orange Caplets

IBUPROFEN

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63548-0185
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	55
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63548-0185-3	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2013	02/02/2025
2	NDC:63548-0185-2	1 in 1 BOX	08/01/2013	02/02/2025
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:63548-0185-1	10 in 1 VIAL; Type 0: Not a Combination Product	08/01/2013	02/02/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076460	08/01/2013	

Labeler - PLD Acquisitions LLC DBA Avéma Pharma Solutions (804087794)

Revised: 1/2025

PLD Acquisitions LLC DBA Avéma Pharma Solutions