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## 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 an 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 oder
- have had stomach ulcers or bleeding problems
- take blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescritpion 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 prdouct

### 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 druing the last 3 months of pegnancy unless defintely 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)

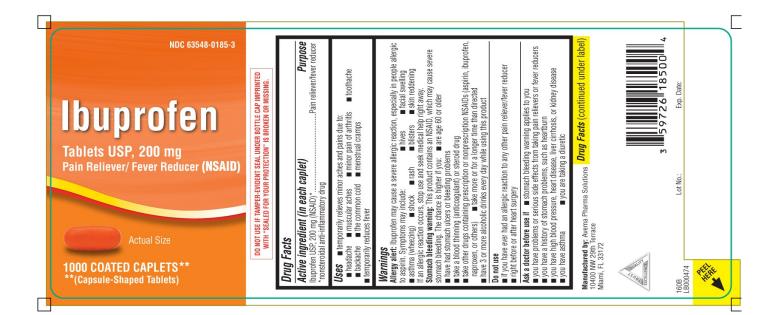
#### DO NOT USE IF TAMPER-EVIDENT SEAL UNDER BOTTLE CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING

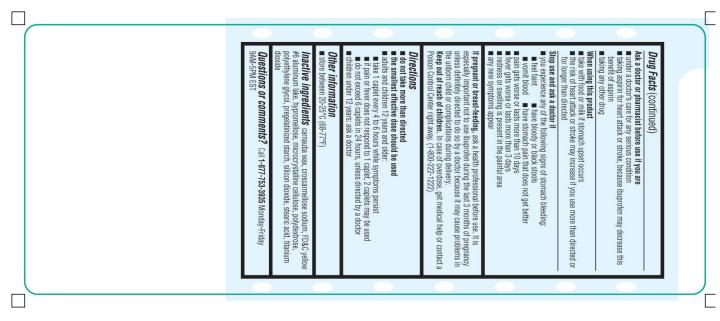
Manufactured by: Avema Pharma Solutions

10400 NW 29th Terrace

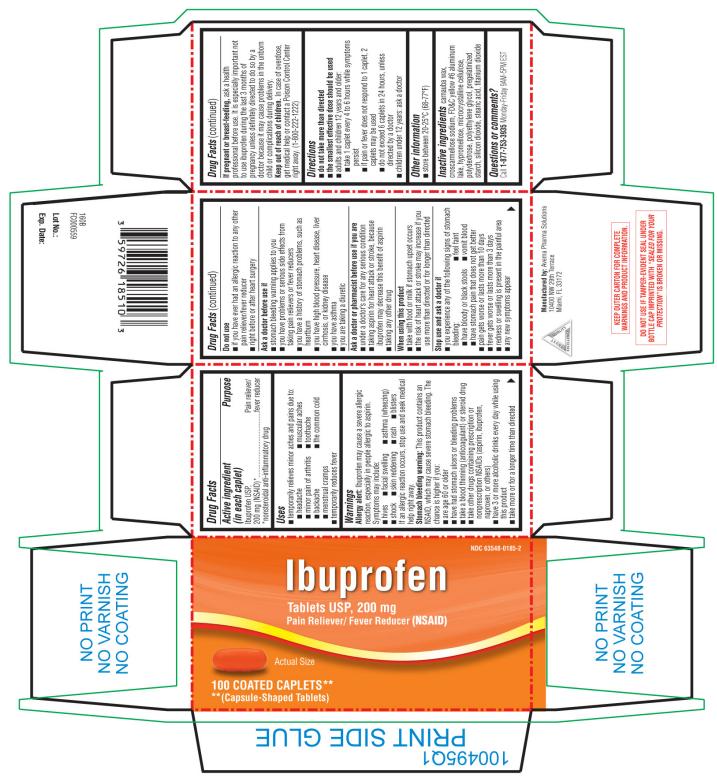
Miami, FL 33172

## Product Label

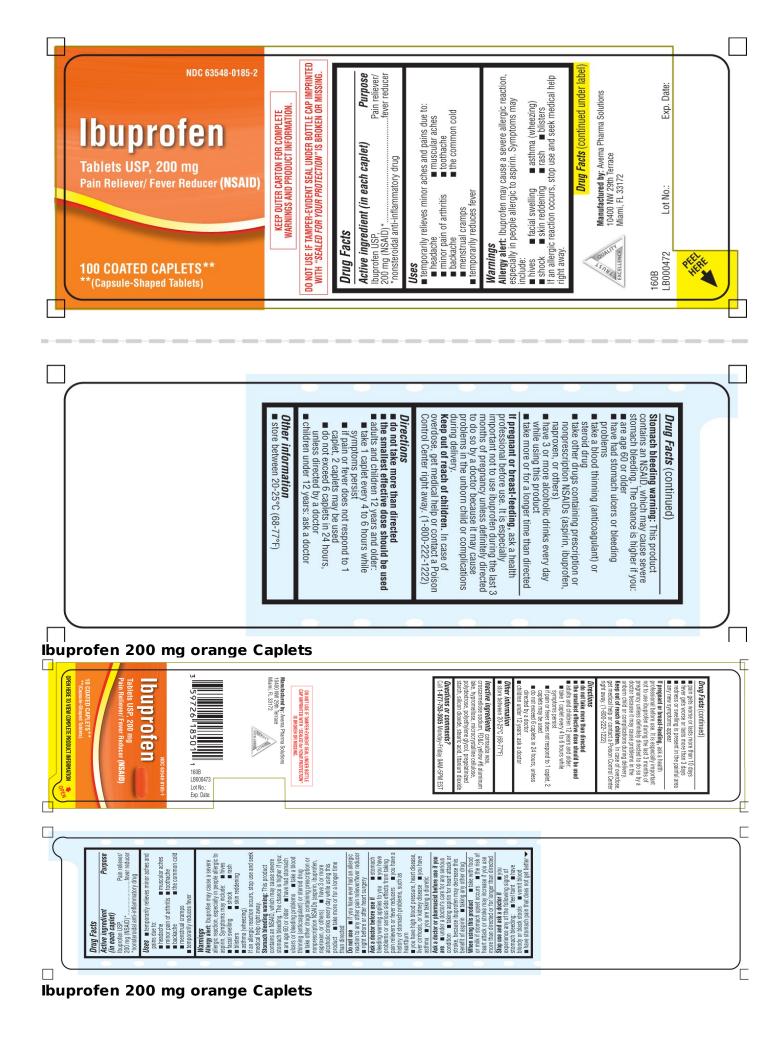








Ibuprofen 200 mg orange Caplets



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DEXTROSE (U			HYPROMELLOSES (UNII: 3NXW29V3WO)								
	JNII: VH2XOU		CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)								
		POLYDEXTROSE (UNII: VH2XOU12IE)									
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)											
STARCH, CORN (UNII: 08232NY3SJ)											
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)											
STEARIC ACID (UNII: 4ELV7Z65AP)											
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)											
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C:63548- 5-3	1000 in 1 BC Product	OTTLE; Type 0: Not a	a Combination	08/01/2013	02,	/02/2025					
C:63548- 5-2	1 in 1 BOX	1 in 1 BOX		08/01/2013	02,	/02/2025					
	100 in 1 BOTTLE; Type 0: Not a Combination Product										
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Marketing Information							
Marketing Category			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