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

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#### **DRUG FACTS**

## Active ingredient (in each tablet)

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 sever 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 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 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, 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 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 tablet every 4 to 6 hours while symptoms persist
  - if pain or fever does not respond to 1 tablet, 2 tablets may be used
  - do not exceed 6 tablets 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 Tablets

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

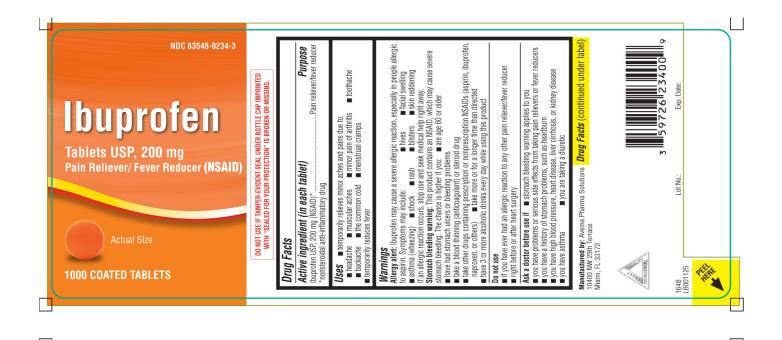
# KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Manufactured by: Avema Pharma Solution

10400 NW 29th terrace

Miami, FL 33172

#### **Product Label**



lbuprofen 200 mg tablets

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Drug Facts (continued)

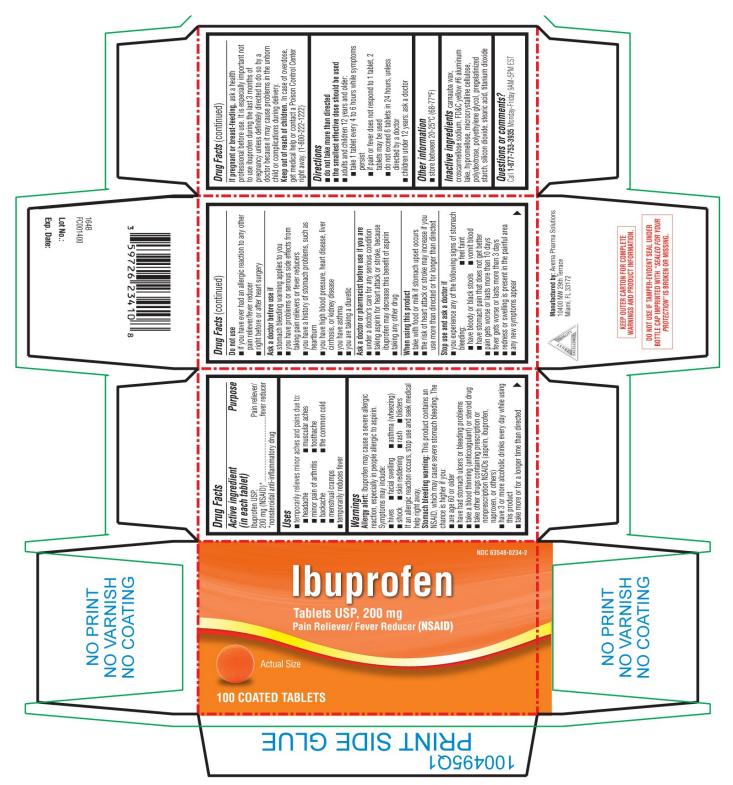
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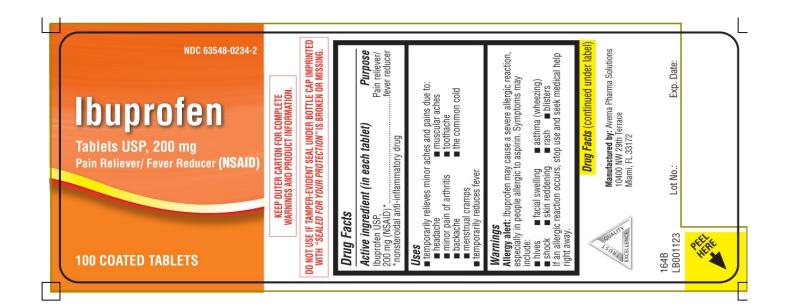
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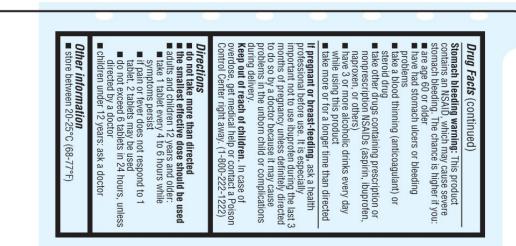
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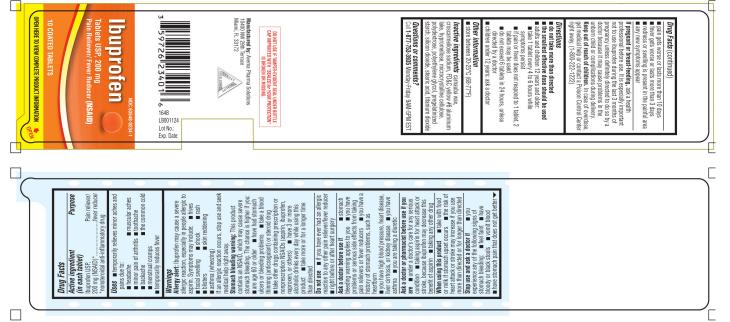


Ibuprofen 200 mg tablets





Ibuprofen 200 mg orange tablet



## Ibuprofen 200 mg orange tablet

## **IBUPROFEN**

ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63548-0234
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)	
CROSCARMELLOSE 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	ROUND	Size	9mm
Flavor		Imprint Code	52
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63548- 0234-1	10 in 1 VIAL; Type 0: Not a Combination Product	08/01/2013		
2	NDC:63548- 0234-2	1 in 1 BOX	08/01/2013		
2		100 in 1 BOTTLE; Type 0: Not a Combination Product			
3	NDC:63548- 0234-3	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2013		

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: 2/2023 PLD Acquisitions LLC DBA Avéma Pharma Solutions