

**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 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 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<sup>o</sup>-25<sup>o</sup>C (68<sup>o</sup>-77<sup>o</sup>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



NO PRINT  
NO VARNISH  
NO COATING

100495Q1  
PRINT SIDE GLUE

# Ibuprofen 200 mg tablets

100 COATED TABLETS



Actual Size

# Ibuprofen

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

NDC 63548-0234-2

Exp. Date:  
Lot No.:  
F0001400  
1618



### 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:
  - muscular aches
  - toothache
  - the common cold
- minor pain of arthritis
- backache
- 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
- skin redness
- asthma (wheezing)
- 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

### Drug Facts (continued)

**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

- you have problems or serious side effects from taking pain relievers or fever reducers
- stomach bleeding warning applies to you
- 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
  - have stomach pain that does not get better
  - rain gets worse or lasts more than 30 days
  - fever gets worse or lasts more than 3 days
  - redness or swelling is present in the painful area
  - any new symptoms appear

### Drug Facts (continued)

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

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

#### Questions or comments?

Call 1-877-753-3835, Monday-Friday 9AM-5PM EST



Manufactured by: Avenite Pharma Solutions  
19400 W. 23rd Terrace  
Miami, FL 33172

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

NDC 63548-0234-2

# Ibuprofen

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

100 COATED TABLETS

KEEP OUTER CARTON FOR COMPLETE  
WARNINGS AND PRODUCT INFORMATION.

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

### Drug Facts

#### Active ingredient (in each tablet)

Ibuprofen USP  
200 mg (NSAID) \* .....fever reducer  
\*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
  - skin reddening
  - rash
  - blisters
- If an allergic reaction occurs, stop use and seek medical help right away.

#### Drug Facts (continued under label)



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

164B  
LB001123

Lot No.:  
Exp. Date:



#### Drug Facts (continued)

**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

**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)

Ibuprofen 200 mg orange tablet

**10 COATED TABLETS**

**OPEN HERE TO VIEW COMPLETE PRODUCT INFORMATION**

**ibuprofen**  
NDC 63548-0234-1

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



5972612540116

1648  
LB001124  
Lot No.:  
Exp. Date:

**DO NOT USE IF PAIN OR FEVER DOES NOT RESPOND TO TREATMENT WITH ASPIRIN OR OTHER PAIN RELIEVERS. ASK YOUR DOCTOR FOR ADVICE ON ASPIRIN USE.**

**Manufactured by:** Avanna Pharma Solutions  
Miami, FL 33172

**Other Information**

■ store between 20°C-25°C (68°-77°F)

**Inactive ingredients:** carnauba wax, croscarmellose sodium, FD&C yellow #6 aluminum lake, hypromellose, hydroxypropyl methylcellulose, polyethylene glycol, polyethylene glycol 400, silicon dioxide, stearic acid, titanium dioxide

**Questions or comments?**  
Call 1-877-353-9898, Monday-Friday 9AM-5PM EST

**Drug Facts (continued)**

- 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 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. **Do not breast-feed or nurse** if you are taking ibuprofen. For more information, ask your health care provider or call the Poison Control Center (800) 992-2222.

**Directions**

- **do not take more than directed**
- **the smallest effective dose should be used**
- adults and children 12 years and older:
  - take 1 to 2 tablets every 4 to 6 hours while symptoms last
  - if pain or fever does not respond to 1 tablet, 2 tablets may be used
  - do not exceed 8 tablets in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

**Other Information**

- store between 20°C-25°C (68°-77°F)

**Inactive ingredients:** carnauba wax, croscarmellose sodium, FD&C yellow #6 aluminum lake, hypromellose, hydroxypropyl methylcellulose, polyethylene glycol, polyethylene glycol 400, silicon dioxide, stearic acid, titanium dioxide

**Questions or comments?**  
Call 1-877-353-9898, Monday-Friday 9AM-5PM EST

### Ibuprofen 200 mg orange tablet

IBUPROFEN			
ibuprofen tablet, coated			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63548-0234
<b>Route of Administration</b>	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg	
Inactive Ingredients			
Ingredient Name	Strength		
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)			
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)			
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)			
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)			
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)			
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)			
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)			
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)			
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)			
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)			
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)			
<b>TITANIUM DIOXIDE</b> (UNII: 15F1X9V2JP)			

**Product Characteristics**

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	52
<b>Contains</b>			

**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