

**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**

NDC 63548-0185-3

# Ibuprofen

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



Actual Size

1000 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.

### Drug Facts

#### Active ingredient (in each caplet)

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

#### Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - minor pain or arthritis
  - backache
  - the common cold
  - temporarily reduces fever
  - toothache
  - menstrual cramps

#### Warnings

**Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- stomach pain
- skin redness

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:

- have had stomach ulcers or bleeding problems
- 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 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

### Drug Facts (continued under label)

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



160B  
L8000474

Lot No.:

Exp. Date:

SEE HERE

### Drug Facts (continued)

#### 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 its 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:
  - belly pain
  - 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

**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

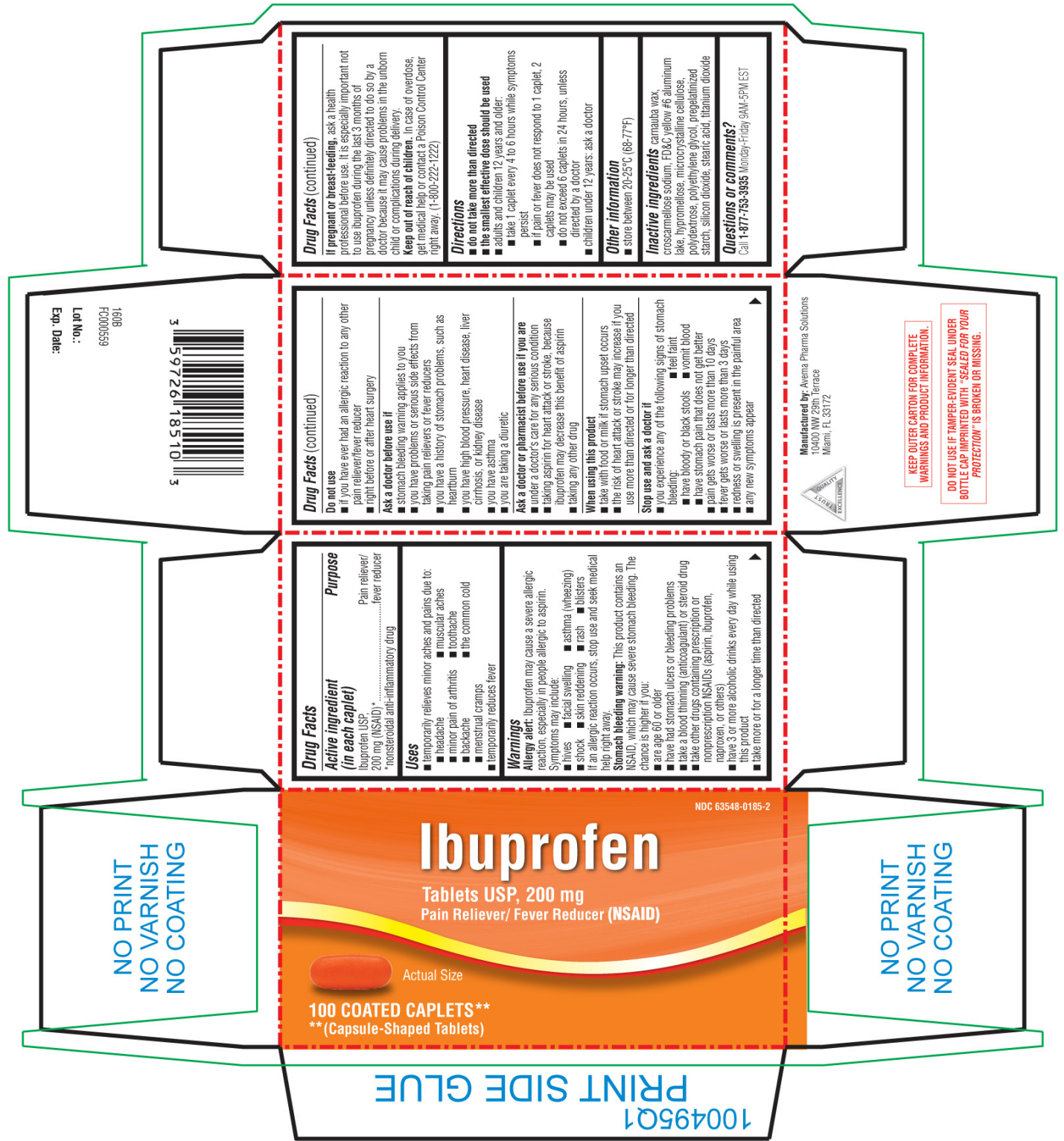
#### Other information

- store between 20-25°C (68-77°F)

**Inactive ingredients:** carnubala wax, 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 1-877-753-3935 Monday-Friday 9AM-5PM EST

Ibuprofen 200 mg orange Caplets



Ibuprofen 200 mg orange Caplets

NO PRINT  
NO VARNISH  
NO COATING

100495Q1  
PRINT SIDE GLUE

# Ibuprofen

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



Actual Size

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

NDC 63548-0185-2

Exp. Date:  
Lot No.:  
1808  
FC00059



### 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
- 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 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

Manufactured by: Avenia Pharma Solutions  
10400 NW 28th 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.

### 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 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 aluminum lake, hydroxymethylcellulose, polydextrose, polyethylene glycol, pregelatinized starch, silicon dioxide, stearic acid, titanium dioxide

### Questions or comments?

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



NDC 63548-0185-2

# Ibuprofen

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

100 COATED CAPLETS\*\*  
\*\*(Capsule-Shaped 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 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
  - 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
- shock
- skin reddening
- asthma (wheezing)
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

#### Drug Facts (continued under label)



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

160B  
LB000472

Exp. Date:

Lot No.:

PEEL  
HERE

### 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 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)

#### Drug Facts (continued)

- start your voice or hoarse more than 10 days after you begin using this product
- 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)

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



160B  
LB000473  
Lot No.:  
Exp. Date:

# Ibuprofen

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

10 COATED CAPLETS\*\*  
\*\*(Capsule-Shaped Tablets)

OPEN HERE TO VIEW COMPLETE PRODUCT INFORMATION

## Ibuprofen 200 mg orange Caplets

## Ibuprofen 200 mg orange Caplets

# IBUPROFEN

ibuprofen tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63548-0185
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<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: O8232NY3S)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	55
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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	02/02/2025

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

Revised: 2/2023

PLD Acquisitions LLC DBA Avéma Pharma Solutions