

IBUPROFEN 200 MG AND DIPHENHYDRAMINE CITRATE 38 MG- ibuprofen, diphenhydramine citrate tablet
PLD Acquisitions LLC DBA Avéma Pharma Solutions

Drug Facts

Active ingredients (in each caplet)

Diphenhydramine citrate 38 mg

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purposes

Nighttime sleep-aid

Pain reliever

Uses

- for relief of occasional sleeplessness when associated with minor aches and pains
- helps you fall asleep and stay asleep

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.

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

Heart attack and stroke warning: NSAIDs except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- unless you have time for a full night's sleep
- in children under 12 years of age
- right before or after heart surgery
- with any other product containing diphenhydramine, even one used on skin
- if you have sleeplessness without pain

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, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have a breathing problem such as emphysema or chronic bronchitis
- you have glaucoma
- you have trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers, or any other sleep-aid
- under a doctor's care for any continuing medical illness
- taking any other antihistamines
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- take any other drug

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery
- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body

- slurred speech
- leg swelling
- pain gets worse or lasts more than 10 days
- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying illness
- 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 (1-800-222-1222) right away.

Directions

- **do not take more than directed**
- adults and children 12 years and over:
 - take 2 caplets at bedtime
 - do not take more than 2 caplets in 24 hours

Other information

- read all warnings and directions before use. Keep carton.
- store between 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive Ingredients

carnauba wax, corn starch, croscarmellose sodium, FD&C blue #2, hypromellose, microcrystalline cellulose, polydextrose, polyethylene glycol 400, silicon dioxide, stearic acid, titanium dioxide

Questions or comments?

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

Principal Display Panel

†Compare to the active ingredients in Advil® PM Caplets

Ibuprofen and Diphenhydramine Citrate Tablets

200 mg/38 mg

Pain reliever (**NSAID**)/Nighttime sleep-aid

20 Coated caplets**

(**Capsule-shaped tablets)

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

†This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor of Advil® PM Caplets.

Manufactured by:

Avéma Pharma Solutions

10400 NW 29th Terrace, Miami, FL 33172

Product Packaging

PRINT SIDE GLUE

Ibuprofen and Diphenhydramine Citrate Tablets

200 mg/38 mg

Pain reliever (NSAID)/Nighttime sleep-aid
20 Coated caplets**
(**Capsule-shaped tablets)

NDC 63548-0197-2
*Compare to the active ingredients in Advil® PM Caplets

120403Q1

Drug Facts

Active ingredients (in each caplet)

Diphenhydramine citrate 38 mg.....Nighttime sleep-aid
Ibuprofen 200 mg (NSAID)*.....Pain reliever
*nonsteroidal anti-inflammatory drug

Uses ■ for relief of occasional sleeplessness when associated with minor aches and pains ■ helps you fall asleep and stay asleep

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.

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
Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure,

Drug Facts (continued)

and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer ■ unless you have time for a full night's sleep ■ in children under 12 years of age ■ right before or after heart surgery ■ with any other product containing diphenhydramine, even one used on skin ■ if you have sleeplessness without pain

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, kidney disease, asthma, or had a stroke ■ you are taking a diuretic ■ you have a breathing problem such as emphysema or chronic bronchitis ■ you have glaucoma ■ you have trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are ■ taking sedatives or tranquilizers, or any other sleep-aid ■ under a doctor's care for any continuing medical illness ■ taking any other antihistamines ■ taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin ■ taking any other drug

When using this product ■ drowsiness will occur ■ avoid alcoholic drinks ■ do not drive a motor vehicle or operate machinery ■ take with food or milk if stomach upset occurs

Drug Facts (continued)

■ store between 20-25°C (68-77°F)
■ avoid excessive heat above 40°C (104°F)

Inactive ingredients carnauba wax, corn starch, croscarmellose sodium, FD&C blue #2, hypromellose, microcrystalline cellulose, polydextrose, polyethylene glycol 400, silicon dioxide, stearic acid, titanium dioxide

Questions or comments? Call

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Drug Facts (continued)

Stop use and ask a doctor if ■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better ■ you have symptoms of heart problems or stroke: ■ chest pain ■ trouble breathing ■ weakness in one part or side of body ■ slurred speech ■ leg swelling ■ pain gets worse or lasts more than 10 days ■ sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness. ■ 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.

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Other information ■ read all warnings and directions before use. Keep carton.

Exp. Date:

Lot No.:

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

This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor of Advil® PM Caplets.



IBUPROFEN 200 MG AND DIPHENHYDRAMINE CITRATE 38 MG

ibuprofen, diphenhydramine citrate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63548-0197
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
DIPHENHYDRAMINE CITRATE (UNII: 4OD433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE CITRATE	38 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3S)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	PL72
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63548-0197-2	1 in 1 BOX	04/11/2024	
1		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:63548-0197-8	8 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/11/2024	
3	NDC:63548-0197-3	300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/11/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211404	04/11/2024	

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

Revised: 4/2024

PLD Acquisitions LLC DBA Avéma Pharma Solutions