

**IBUPROFEN AND DIPHENHYDRAMINE HCL- ibuprofen, diphenhydramine
hcl capsule, liquid filled
EQUATE (Wal-Mart Stores, Inc.)**

Drug Facts

Active ingredient (in each capsule)

Diphenhydramine hydrochloride 25 mg

**Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)
(present as the free acid and potassium salt)**

***non-steroidal anti-inflammatory drug**

Purpose

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:

- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- 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

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

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have glaucoma
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a breathing problem such as emphysema or chronic bronchitis
- 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
- taking any other drug
- taking any other antihistamines
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any continuing medical illness

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
- 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
- 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.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

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

Other information

- each capsule contains: **potassium 20 mg**
- read all warnings and directions before use. Keep carton.
- store at 20° to 25°C (68° to 77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- do not chew or crush prior to swallowing
- protect from light

Inactive ingredients

FD&C blue #1, FD&C red #40, gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan, sorbitol

Questions or comments?

Call **1-888-287-1915**

Principal Display Panel

Compare to Advil® PM Liqui-Gels® Active Ingredients**

Ibuprofen PM Softgels

Ibuprofen 200 mg

Diphenhydramine HCl, 25 mg

Pain Reliever (NSAID) / Nighttime Sleep-Aid

NIGHTTIME

SOFTGELS**

(**liquid filled capsules)

**This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Advil® PM LIQUI-GELS®.


KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

**DISTRIBUTED: BY Wal-Mart Stores, Inc.,
Bentonville, AR 72716**

Product Packaging

NDC 49035-065-40



Compare
to Advil®
PM Liqui-Gels®
Active
Ingredients**


Ibuprofen PM Softgels

Ibuprofen, 200 mg
Diphenhydramine HCl, 25 mg

**Pain Reliever (NSAID)/
Nighttime Sleep-Aid**

40
SOFTGELS*

*Liquid Filled
Capsules



Actual Size

Drug Facts

Active ingredients (in each capsule)	Purposes
Diphenhydramine hydrochloride 25 mg.....	Nighttime sleep-aid
Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)*.....	Pain reliever (present as the free acid and potassium salt)
*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: ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ are age 60 or older ■ 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 ■ in children under 12 years of age ■ if you have ever had an allergic reaction to any

Drug Facts (continued)

other pain reliever/fever reducer ■ right before or after heart surgery ■ unless you have time for a full night's sleep ■ with any other product containing diphenhydramine, even one used on skin ■ if you have sleeplessness without pain

Ask a doctor before use if ■ the stomach bleeding warning applies to you ■ you have a history of stomach problems, such as heartburn ■ you have glaucoma ■ you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma ■ you are taking a diuretic ■ you have problems or serious side effects from taking pain relievers or fever reducers ■ you have a breathing problem such as emphysema or chronic bronchitis ■ 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 ■ taking any other drug ■ taking any other antihistamines ■ taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin ■ under a doctor's care for any continuing medical illness

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 ■ 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

Drug Facts (continued)

■ have stomach pain that does not get better
■ 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.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions ■ do not take more than directed ■ adults and children 12 years and over:
■ take 2 capsules at bedtime
■ do not take more than 2 capsules in 24 hours

Other information ■ each capsule contains: potassium 20 mg ■ read all warnings and directions before use. Keep carton. ■ store at 20° to 25°C (68° to 77°F) ■ avoid high humidity and excessive heat above 40°C (104°F) ■ protect from light


Inactive ingredients FD&C blue #1, FD&C red #40, gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan, sorbitol

Questions or comments? Call 1-888-287-1915

Lot No.:

Exp. Date:

Equate Ibuprofen PM Softgels



DO NOT USE IF TAMPER-EVIDENT SEAL UNDER BOTTLE
IS BROKEN OR MISSING.

KEEP OUT OF REACH OF CHILDREN FOR COMPLETE
WARNINGS AND PRODUCT INFORMATION.

Satisfaction guaranteed - For questions
or comments please call 1-888-287-1915.

DISTRIBUTED BY: Wal-Mart Stores, Inc.,
Bentonville, AR 72716
*This product is not manufactured or distributed by
registered trademark Advil® PM LIQUI-GELS®.
PLD-A112E FC003101 Rev# 09/12

IBUPROFEN AND DIPHENHYDRAMINE HCL

ibuprofen, diphenhydramine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-065
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-065-40	1 in 1 BOX	12/31/2015	04/26/2024
1		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090397	12/31/2015	04/26/2024

Labeler - EQUATE (Wal-Mart Stores, Inc.) (051957769)