

ACETAMINOPHEN PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl tablet, coated

EQUATE (Wal-Mart Stores, Inc.)

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever

Nighttime sleep-aid

Uses

temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness.

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on skin
- in children under 12 years of age

Ask a doctor before use if you have

- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed (see overdose warning)**
- adults and children 12 years and over: take 2 caplets at bedtime. Do not take more than 2 caplets of this product in 24 hours.
- children under 12 years: do not use

Other information

- store at room temperature 15°-30°C (59°-86°F)
- avoid high humidity and excessive heat

Inactive ingredients

croscarmellose sodium*, D&C yellow #10 aluminum lake*, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake*, hypromellose, magnesium silicate*, magnesium stearate*, microcrystalline cellulose*, mineral oil*, polyethylene glycol*, povidone, pregelatinized starch, silica*, sodium starch glycolate*, stearic acid, titanium dioxide, triacetin*

*contains one or more of these ingredients

Questions or comments?

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

Principal Display Panel

Compare to Extra Strength Tylenol® PM Active Ingredients**

Extra Strength

Acetaminophen PM

Acetaminophen 500 mg, Diphenhydramine HCl 25 mg

Pain Reliever/Nighttime Sleep Aid

Aspirin Free

Non-Habit Forming

CAPLETS

**This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol® PM

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

Distributed by: Wal-Mart Stores, Inc.

Bentonville, AR 72716

**This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol® PM.

Product Label

Exp. Date:
Lot No.:
FC001588
PLD-A



Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg.....Pain reliever
Diphenhydramine HCl 25 mg.....Nighttime sleep-aid

Uses temporary relief of occasional headaches and minor aches and pains with accompanying sleepiness.

Warnings

Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take:
 ■ more than 4,000 mg of acetaminophen in 24 hours
 ■ with other drugs containing acetaminophen
 ■ 3 or more alcoholic drinks every day while using this product

Do not use

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 ■ with any other product containing diphenhydramine, even one used on skin
 ■ in children under 12 years of age

Ask a doctor before use if you have

■ liver disease
 ■ a breathing problem such as emphysema or chronic bronchitis
 ■ trouble urinating due to an enlarged prostate gland
 ■ glaucoma

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are

■ taking the blood thinning drug warfarin
 ■ taking sedatives or tranquilizers

When using this product

■ drowsiness will occur
 ■ avoid alcoholic drinks
 ■ do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

■ sleepiness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
 ■ new symptoms occur
 ■ redness or swelling is present
 ■ pain gets worse or lasts more than 10 days
 ■ fever gets worse or lasts more than 3 days
 These could be signs of a serious condition.

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Drug Facts (continued)

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Satisfaction guaranteed - Or we'll replace it or give you your money back. For questions or comments or to report an undesired reaction or side effect, please call 1-888-287-1915.

Distributed by: Wal-Mart Stores, Inc., Bentonville, AR 72716 © Wal-Mart Stores, Inc.
 **This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol® PM.

equate®

NDC 49035-013-50

Extra Strength

Acetaminophen PM

Acetaminophen 500mg, Diphenhydramine HCl 25mg

Pain Reliever/Nighttime Sleep Aid

Aspirin Free

Non-Habit Forming

**50
CAPLETS**

Compare to
Extra Strength
Tylenol® PM
Active
Ingredients**

Actual Size

Equate Extra Strength Acetaminophen PM Caplet

ACETAMINOPHEN PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-013
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
ALUMINUM OXIDE (UNII: LM26O6933)	

Product Characteristics

Color	BLUE	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	S525;CPC752
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:49035-013-50	1 in 1 BOX	09/30/2013	12/31/2020
1		50 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
OTC MONOGRAPH FINAL	part341	09/30/2013	12/31/2020

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

Revised: 12/2018

EQUATE (Wal-Mart Stores, Inc.)