PAIN RELIEVER PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl tablet, coated

EQUATE (Wal-Mart Stores, Inc.) (see also WAL-MART INC)

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

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

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 products containing diphenhydramine, even one used on skin
- in children under 12 years of age
- if you have ever had an allergic reaction to this product or any of its ingredients

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 for more than 10 days
- fever gets worse or lasts for 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 (1-800-222-1222) 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 between 20-25°C (68-77°F)
- avoid high humidity and excessive heat

Inactive ingredients

croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol,

polyvinyl alcohol, povidone K30, pregelatanized starch, purified water, silicon dioxide, sodium starch glycolate, talc, titanium dioxide

Questions or comments?

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

Principal Display Panel

[†]Compare to the active ingredients in Extra strength Tylenol® PM

Extra Strength

Pain Reliever PM

Acetaminophen 500 mg Pain reliever

Diphenhydramine HCL 25 mg Nighttime Sleep Aid

Non-Habit Forming

For ages 123 years and over

Caplets

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Extra Strength Tylenol® PM.

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

Distributed by: Wal-Mart Inc.,

Bentonville, AR 72716

Package Label



EQUATE Pain Reliever PM

Lot No.: Exp. Date:

PAIN RELIEVER PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-363
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	ACETAMINOPHEN	500 mg	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)

HYPROMELLOSES (UNII: 3NXW29V3WO)

MAGNESIUM STEARATE (UNII: 70097M6I30)

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3MJQ0SDW1A)

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)

POVIDONE K30 (UNII: U725QWY32X)

STARCH, CORN (UNII: 08232NY3SJ)

WATER (UNII: 059QF0KOOR)

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

ALUMINUM OXIDE (UNII: LMI2606933)

Product Characteristics			
Color	blue	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	P525
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035- 363-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/31/2020	
2	NDC:49035- 363-25	225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/31/2020	
3	NDC:49035- 363-24	1 in 1 BOX	01/31/2020	
3		24 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 Drug	M013	01/31/2020	

Labeler - EQUATE (Wal-Mart Stores, Inc.) (see also WAL-MART INC) (051957769)

Revised: 3/2024 EQUATE (Wal-Mart Stores, Inc.) (see also WAL-MART INC)