ACETAMINOPHEN, DIPHENHYDRAMINE HCL- acetaminophen, diphenhydramine hcl tablet, film coated
CVS Pharmacy, Inc.

0752-CVS

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever and Nighttime sleep-aid

Uses

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

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 product containing diphenhydramine, even one used on skin
- in children under 12 years of age
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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
- difficulty in urination due to enlargement of the 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
- avoid alcoholic beverages
- do not drive a motor vehicle or operate machinery
- drowsiness will occur

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.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt 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**
- **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 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

croscarmellose sodium, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, hypromellose, magnesium stearate, mineral oil, polyvinylpyrrolidone, pregelatinized starch, silica, sodium starch glycolate, stearic acid, talc, titanium dioxide, triacetin

Questions or comments?

1-800-231-4670

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

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

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

CVS.com® 1-800-SHOP CVS

V-34571

CVSHealth

Compare to the active ingredients in Extra Strength Tylenol® PM*

EXTRA STRENGTH

Acetaminophen PM

ACETAMINOPHEN, 500 mg

DIPHENHYDRAMINE HCl, 25 mg

Pain reliever/Nighttime sleep aid

Package Contains One Bottle

100 CAPLETS

ACETAMINOPHEN, DIPHENHYDRAMINE HCL

acetaminophen, diphenhydramine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-572
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
TRIACETIN (UNII: XHX3C3X673)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	CPC752
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-572-08	1 in 1 CARTON	07/23/2018	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69842-572-15	1 in 1 CARTON	07/23/2018	06/30/2021
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69842-572-12	1 in 1 CARTON	07/23/2018	

3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69842-572-29	150 in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2018	
5	NDC:69842-572-02	1 in 1 CARTON	02/02/2023	
5		225 in 1 BOTTLE; 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	07/23/2018	

Labeler - CVS Pharmacy, Inc. (062312574)

Revised: 1/2024 CVS Pharmacy, Inc.