

ACETAMINOPHEN AND DIPHENHYDRAMINE HYDROCHLORIDE- acetaminophen and diphenhydramine hydrochloride tablet, film coated
WALMART 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.

ACETAMINOPHEN AND DIPHENHYDRAMINE HCL TABLETS

Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 500mg	Pain reliever
Diphenhydramine HCl 25mg	Nighttime Sleep aid

Uses

for the 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 with this product if you take

- more than 2 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while you are using this product

Do not use

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

Ask a doctor before use if you have

- liver cirrhosis
- asthma
- breathing problems such as emphysema or chronic bronchitis
- trouble in urinating due to an 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

- 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
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

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

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 recommended** (see overdose warning)

adults and children 12 years of age and over:	<ul style="list-style-type: none">▪ take 2 caplets at bedtime or as directed by a doctor▪ do not take more than 2 caplets in a 24 hour period
children under 12 years of age:	<ul style="list-style-type: none">▪ do not use this adult product in children under 12 years of age. This will provide more than the recommended dose (overdose) and may cause liver damage

Other information

- store at 20°-25°C (68°-77°F)
- see end panel for lot number and expiration
- each tablet contains: **magnesium 0.05 mg**

Inactive ingredients

FD&C blue # 1, FD&C blue # 2, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol-400, pregelatinized starch, povidone, stearic acid, titanium dioxide

Questions or comments?

1-888-287-1915

Distributed by: Wal-Mart Stores, Inc., Bentonville, AR 72716

PRINCIPAL DISPLAY PANEL - 50 Caplet Bottle Carton

NDC 49035-026-50

equate[®]

**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**

**50
CAPLETS**

Actual Size

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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(in each caplet)
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Pain relief
Nighttime Sleep aid

Uses for the 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 with this product if you take more than 2 caplets in 24 hours, which is the maximum daily amount.
Do not use with other products containing acetaminophen, ask a doctor or pharmacist.
If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
Do not use in children under 12 years of age.
Do not use with any other products containing diphenhydramine, even one used on skin.
If you are allergic to acetaminophen or any of the inactive ingredients in this product.
Ask a doctor before use if you have:
Liver cirrhosis asthma

Drug Facts (continued)
breathing problems such as emphysema or chronic bronchitis
trouble in urinating due to an enlargement of the prostate gland
diabetes
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
pain gets worse or lasts for more than 10 days
fever gets worse or lasts more than 3 days
new symptoms occur
rash or sore throat is present
These could be signs of a serious condition, pregnant or breast-feeding, ask a health professional before use, keep out of reach of children.

Overdose Warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Drug Facts (continued)

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Do not take more than recommended (see overdose warning)
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Use 2 caplets at bedtime or as directed by a doctor
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do not use this adult product in children under 12 years of age. This will provide more than the recommended dose (overdose) and may cause liver damage

Other Information

store at 20°-25°C (68°-77°F)
see end panel for lot number and expiration
each tablet contains: magnesium 0.165 mg
inactive ingredients
FDAC like # 1, FDAC like # 2, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol-400, polyethylene glycol, polydioxane, stearic acid, titanium dioxide

Questions or comments? 1-888-287-1915
Satisfaction guaranteed - for questions or comments please call 1-888-287-1915.
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Lot:
Exp. Date:

NO INK OR AQ

NDC 4905-026-50



Extra Strength
Acetaminophen PM
Acetaminophen 500 mg, Diphenhydramine HCl 25 mg
Pain Reliever/Nighttime Sleep Aid
Aspirin Free
Non-Habit Forming

50 CAPLETS

Compare to Extra Strength Tylenol® PM Active Ingredients*

Actual Size

NO INK OR AQ

NO INK OR AQ

NO INK OR AQ

ACETAMINOPHEN AND DIPHENHYDRAMINE HYDROCHLORIDE

acetaminophen and diphenhydramine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-026
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
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	BLUE	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	S525
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-026-50	1 in 1 CARTON		
1		50 in 1 BOTTLE		
2	NDC:49035-026-20	2 in 1 CARTON		
2		100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	06/01/2014	

Labeler - WALMART STORES INC (051957769)**Establishment**

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LTD		858352983	MANUFACTURE(49035-026)

