

**ACETAMINOPHEN / DIPHENHYDRAMINE 500/25 MG- acetaminophen /  
diphenhydramine tablet**

**Reliable 1 Laboratories LLC**

*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.*

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**ACETAMINOPHEN / DIPHENHYDRAMINE 500/25 MG CAPLET**

***Drug Facts***

Acetaminophen 500 mg

Diphenhydramine HCL 25 mg

Pain reliever

Nighttime sleep aid

temporarily relieves 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 which is the maximum daily amount
- 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 doctor or pharmacist.
- with any other drug containing diphenhydramine, even one used on skin
- in children under 12 years of age

**Ask a doctor before use if you have**

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

***Drug Facts*** continued on back of label

**Ask a doctor or pharmacist before use if you are**

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

**When using this product**

- marked drowsiness will occur
- avoid alcoholic drinks

- alcohol, sedatives and tranquilizers may increase droqsiness
- do not drive a motor vehicle or operate machinery

### **Stop use and ask a doctor if**

- sleeplessness lasts 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 for more than 3 days
- redness or swelling is present
- new symptoms occur

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. Incase of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children, even if you do not notice 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 if needed
- do not take more than directed

**children under 12 years: do not use**

### ***Other information***

store at room temperature 15°-30°C (59°-86°F)

croscarmellose sodium, FD&C blue #1, hypromellose, microcrystalline cellulose, polyethylene glycol 400, povidone, pregelatinized corn starch, silicon dioxide, stearic acid, titanium dioxide

call **516-341-0666**, 8:30 am- 4:30 pm ET, Monday-Friday

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

\*Reliable 1 Laboratories LLC is not affiliated with the owner of the trademark Tylenol® PM

Distributed by: **Reliable 1 Laboratories LLC, Valley Stream, NY 11580**

**www.reliable1labs.com**

NDC 69618-013-06



**Acetaminophen  
500 mg &  
Diphenhydramine  
HCl 25 mg**

**PAIN RELIEVER  
NIGHTTIME SLEEP AID**

**50 CAPLETS**

\*Compare to Active Ingredients in Tylenol® PM

**Drug Facts**

**Active ingredients (in each caplet)** *Purposes*  
Acetaminophen 500 mg ..... Pain reliever  
Diphenhydramine HCl 25 mg ..... Nighttime sleep aid

**Uses** Temporarily relieves occasional headaches and minor aches and pains with accompanying sleepiness

**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 which is the maximum daily amount.
- with other drugs containing acetaminophen
- and/or more alcoholic drinks every day while using this product

**Allergy alert:** acetaminophen may cause severe skin reactions. Symptoms may include:  
 skin reddening    hives    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 drug containing diphenhydramine, even one used on skin
- in children under 12 years of age

**Ask a doctor before use if you have**  
 liver disease    glaucoma  
 trouble urinating due to an enlarged prostate gland  
 any breathing problem such as emphysema or chronic bronchitis

**Drug Facts continued on back of label**

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

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Rev. 0615  
 3 69618 01305 6

Lot No.:  
 Exp. Date:

**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**  

- alcohol, drowsiness and tranquilizers may increase drowsiness
- do not drive a motor vehicle or operate machinery

**Stop use and ask a doctor if**  

- drowsiness lasts 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 for more than 3 days
- redness or swelling is present
- new symptoms occur

 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. 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 (see overdose warning) adults and children 12 years and over:
- take 2 caplets at bedtime if needed
- do not take more than directed
- children under 12 years: do not use

**Other information**  
 store at room temperature 15°-30°C (59°-86°F)

**Inactive ingredients**  
 croscarmellose sodium, FD&C Blue #1, hypromellose, microcrystalline cellulose, polyethylene glycol 400, povidone, pregelatinized corn starch, silicon dioxide, stearic acid, titanium dioxide

**Questions or comments?** call 516-941-0986, 8:30 am - 4:30 pm ET, Monday-Friday

NDC 69618-013-05

Acetaminophen 500 mg & Diphenhydramine HCL 25 mg

PAIN RELIEVER

NIGHTTIME SLEEP AID

50 CAPLETS

\*Compare to Active Ingredients in Tylenol® PM

**ACETAMINOPHEN / DIPHENHYDRAMINE 500/25 MG**

acetaminophen / diphenhydramine tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69618-013
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

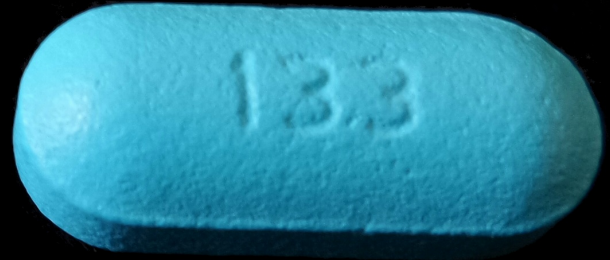
Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	blue (Light Blue)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	AP;133
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69618-013-05	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2015	



# Acetaminophen 500mg/ Diphenhydramine 25mg Tablets

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	11/01/2015	

**Labeler** - Reliable 1 Laboratories LLC (079718111)

Revised: 1/2016

Reliable 1 Laboratories LLC