

**ACETAMINOPHEN AND DIPHENHYDRAMINE HYDROCHLORIDE- acetaminophen and diphenhydramine hydrochloride tablet**  
**Granules India Limited**

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**Acetaminophen 500mg Diphenhydramine HCl 25mg Tablets**

**ACTIVE INGREDIENT**

(in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25mg

**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 product 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 serious underlying medical illness.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

## **PREGNANCY OR BREAST FEEDING**

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**

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 this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

## INACTIVE INGREDIENTS

colloidal silicon dioxide, croscarmellose sodium, hypromellose, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, stearic acid, titanium dioxide

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

# ACETAMINOPHEN 500 mg AND DIPHENHYDRAMINE HCl 25 mg TABLETS

Each Film coated tablet contains:

Acetaminophen USP 500 mg and Diphenhydramine HCl USP 25 mg

Batch No. : XXXXXXX

No. of Units : 77,670 Tablets

Mfg.Dt. : MM/YYYY

Exp.Dt. : MM/YYYY

Mfg.Lic.No. : 37/RR/AP/2003/F/R

NDC No. : 62207-661-94

Storage : Store at controlled room temperature [store at 20°-25°C (68°- 77°F);  
excursions permitted to 15°-30°C (59°-86°F); preserve in tightly closed containers.]

Caution :For repacking only.

Country of Origin: INDIA

Sujani  
Pillapal  
em

Digitally signed  
by Sujani  
Pillapalem  
Date:  
2019.04.08  
09:55:42 +05'30'

Product code : 70000001859

# ACETAMINOPHEN 500 mg AND DIPHENHYDRAMINE HCl 25 mg TABLETS

Each Film coated tablet contains:

Acetaminophen USP 500 mg and Diphenhydramine HCl USP 25 mg

Batch No. : XXXXXXX	No. of Units : 77,670 Tablets
Mfg.Dt. : MM/YYYY	Gross Wt. : 00.000 Kg
Exp.Dt. : MM/YYYY	Tare Wt. : 00.000 Kg
Mfg.Lic.No. : 37/RR/AP/2003/F/R	Net Wt. : 00.000 Kg
NDC No. : 62207-661-94	Drum number : 000

Storage : Store at controlled room temperature [store at 20°-25°C (68°- 77°F); excursions permitted to 15°-30°C (59°-86°F); preserve in tightly closed containers.]

Caution : For repacking only.



(01)50362207661947(17)000000(10)XXXXXXX

Country of Origin: INDIA



(00)189038320000000004

Product code : 700000001859

Sujani Pillapalem

Digitally signed by  
Sujani Pillapalem  
Date: 2019.04.08  
09:55:02 +05'30'

# ACETAMINOPHEN 500 mg AND DIPHENHYDRAMINE HCl 25 mg TABLETS

Each Film coated tablet contains:

Acetaminophen USP 500 mg and Diphenhydramine HCl USP 25 mg

Batch No. : XXXXXXX	No. of Units : 125,000 Tablets
Mfg.Dt. : MMM/YYYY	Gross Wt. : 00.000 Kg
Exp.Dt. : MMM/YYYY	Tare Wt. : 00.000 Kg
Mfg.Lic.No.: 37/RR/AP/2003/F/R	Net Wt. : 00.000 Kg
NDC No. : 62207-661-78	Drum number : 000

Storage : Store at controlled room temperature [store at 20°-25°C (68°- 77°F); excursions permitted to 15°-30°C (59°-86°F); preserve in tightly closed containers.]

Caution : For repacking only.



(01)28903832302662(17)000000(10)XXXXXXX

Country of Origin: INDIA



(00)189038320000000004

Product code : F4003K10

GIL/PL/041C



Manufactured by:

**Granules India Limited**

Sy.No.160/A, 161/E, 162, & 174/A, Gagillapur Village,  
Dundigal-Gandimaisamma Mandal, Medchal-Malkajgiri District - 500043,  
Telangana, INDIA

# ACETAMINOPHEN 500 mg AND DIPHENHYDRAMINE HCl 25 mg TABLETS

Each Film coated tablet contains:

Acetaminophen USP 500 mg and Diphenhydramine HCl USP 25 mg

Batch No. : XXXXXXXX No. of Units : 125,000 Tablets

Mfg.Dt. : MMM/YYYY

Exp.Dt. : MMM/YYYY

Mfg.Lic.No. : 37/RR/AP/2003/F/R

NDC No. : 62207-661-78

Storage : Store at controlled room temperature.

Caution : For repacking only.

Country of Origin: INDIA



Manufactured in India by:

**Granules India Limited**

Plot No. 160/A, 161/E, Gagillapur Village,  
Qutbullapur Mandal, Ranga Reddy Dt - 500 043, AP.

Product code : F4003K10

## ACETAMINOPHEN AND DIPHENHYDRAMINE HYDROCHLORIDE

acetaminophen and diphenhydramine hydrochloride tablet

### Product Information

Product Type	BULK INGREDIENT	Item Code (Source)	NDC:62207-661
Route of Administration	NOT APPLICABLE		

### 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
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL (caplet-shaped)	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	G651
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-661-78	125000 in 1 DRUM	12/05/2014	
2	NDC:62207-661-94	77670 in 1 DRUM	06/14/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		12/05/2014	

**Labeler** - Granules India Limited (915000087)

**Registrant** - Granules India Limited (915000087)

### Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		918609236	manufacture(62207-661)