

**ACETAMINOPHEN DIPHENHYDRAMINE HCL- acetaminophen diphenhydramine  
hcl tablet  
WALGREEN CO.**

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**Combo Pack**

**Pain reliever Acetaminophen USP, 500mg  
Pain releiver/fever reducer  
Extra strength**

**Pain reliever PM  
Acetaminophen USP, 500mg/Diphenhydramine HCL USP, 25mg  
Pain reliever/ Nighttime sleep-aid  
Nighttime  
Extra strength**

**Acetaminophen Gelcaps Active Ingredient (in each Gelcap)**

Acetaminophen USP, 500 mg

**Purpose**

Pain reliever/fever reducer

**Uses**

- temporarily relieves minor aches and pains due to:
- headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- premenstrual and menstrual cramps
- temporarily reduces fever

**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
- 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

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

taking the blood thinning drug warfarin.

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

- pain gets worse or lasts 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 the reach of children.**

Keep out of the reach of children.

### **Overdose Warning**

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 (see overdose warning)**

adults and children 12 years and over

- take 2 gelcaps every 6 hours while symptoms last
- do not take more than 6 gelcaps in 24 hours, unless directed by a doctor
- do not take more than 10 days unless directed by a doctor

children under 12 years

- ask a doctor

## **Other information**

- store at 20°-25°C (68°-77°F). See USP Controlled Room Temperature
- avoid high humidity
- see end panel for lot number and expiration date

## **Inactive ingredients**

ammonium hydroxide, black iron oxide, colloidal silicon dioxide, croscarmellose sodium, D&C red#33, FD&C blue#1, FD&C red#40, FD&C yellow#6, gelatin, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, hypromellose, iron oxide red, isopropyl alcohol, n-butyl alcohol, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, stearic acid, titanium dioxide, yellow iron oxide.

## **Questions or comments?**

call **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST.

## **Acetaminophen PM Gelcaps Active ingredient (in each gelcap)**

Acetaminophen USP, 500 mg

Diphenhydramine HCl USP, 25 mg

## **Purposes**

Pain reliever

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 drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other 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 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.

## **If pregnant or breast-feeding,**

ask a health professional before use.

## **Keep out of the reach of children.**

Keep out of the 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 (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 gelcaps at bedtime
- do not take more than 2 gelcaps of this product in 24 hours  
children under 12 years
- do not use

## **Other information**

■ store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature.

■ see end panel for lot number and expiration date

## Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D7C red#28, D&C yellow#10, FD7C blue#1, FD&C blue #2, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, isopropyl alcohol, microcrystalline cellulose, n-butyl alcohol, povidone, pregelatinized starch, propylene glycol, shellac glaze, stearic acid, titanium dioxide, triacetin.

## Questions or comments?

call **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST.

## Principal Display Panel



# ACETAMINOPHEN DIPHENHYDRAMINE HCL

acetaminophen diphenhydramine hcl tablet

## Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:0363-9799

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
TRIACETIN (UNII: XHX3C3X673)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
GELATIN (UNII: 2G86QN327L)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
SHELLAC (UNII: 46N107B71O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
AMMONIA (UNII: 5138Q19F1X)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POVIDONE (UNII: FZ989GH94E)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

### Product Characteristics

Color	gray (Encapsulated gray color tablets with one red opaque and one blue-gray opaque hard gelatin shells) , gray (Encapsulated gray color tablets with dark blue opaque and light blue opaque hard gelatin shells)	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	G1;G3
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9799-75	75 in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	03/03/2023	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	03/03/2023	

**Labeler** - WALGREEN CO. (008965063)

Revised: 12/2024

WALGREEN CO.