

**ACETAMINOPHEN DIPHENHYDRAMINE HCL- acetaminophen diphenhydramine  
hcl tablet  
CVS PHARMACY, 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.*

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**EXTRA STRENGTH  
Acetaminophen  
Gelcaps USP, 500 mg  
&  
EXTRA STRENGTH  
Acetaminophen PM  
ACETAMINOPHEN, USP 500 mg  
DIPHENHYDRAMINE HCl, USP 25 mg**

**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 a 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.**

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 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, black iron oxide irradiated, colloidal silicon dioxide, croscarmellose sodium, 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 9:00 AM to 4:30 PM EST.

## **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 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.

### **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, 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.

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**DAY & NIGHT COMBO PACK**

**CVS Health**

**EXTRA STRENGTH**  
**Acetaminophen**  
Gelcaps USP, 500 mg  
Pain reliever;  
Fever reducer  
Aspirin free

**EXTRA STRENGTH**  
**Acetaminophen PM**  
ACETAMINOPHEN, USP 500 mg  
DIPHENHYDRAMINE HCl, USP 25 mg  
Pain reliever;  
Nighttime sleep aid

**Drug Facts (continued)**

**Warnings**  
Liver warnings: 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  
Always alert acetaminophen may cause severe skin reactions. Symptoms may include:  
■ skin redness  
■ 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  
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 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 more than 10 days  
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**Other Information**  
■ store at 20°-25°C (68°-77°F). See USP Controlled Room Temperature.  
■ avoid high humidity.  
■ see end panel for expiration date and lot number.

**Questions or comments?**  
call 1-877-770-3183 Mon-Fri 9:00 AM to 4:30 PM EST.

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Made in India  
V-3557

**CVS Quality**  
Money Back Guarantee

**Actual Size**  
50 GELCAPS

**Actual Size**  
50 GELCAPS  
100 TOTAL

**Package Contains**  
Two Bottles

**Lot**  
**Exp.**

**#361922**

**300000388**  
**525000023**  
**R-00**

**300000388**  
**525000023**  
**R-00**

## ACETAMINOPHEN DIPHENHYDRAMINE HCL

acetaminophen diphenhydramine hcl tablet

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	
Route of Administration		ORAL	NDC:69842-308	
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
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
GELATIN (UNII: 2G86QN327L)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
AMMONIA (UNII: 5138Q19F1X)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TRIACETIN (UNII: XHX3C3X673)				
FERROSOFERRIC OXIDE (UNII: XM0M87F357)				
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)				
POVIDONE (UNII: FZ989GH94E)				
STARCH, CORN (UNII: O8232NY3SJ)				
SHELLAC (UNII: 46N107B71O)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
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:69842-308-10	100 in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	01/29/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part343		01/29/2019	

**Labeler -**
CVS PHARMACY, INC (062312574)