

**VALUMEDS PAIN RELIEF PM PAIN RELIEVER AND NIGHTTIME SLEEP AID
ACETAMINOPHEN, EXTRA STRENGTH- acetaminophen, diphenhydramine
hydrochloride tablet
Cabinet Health P.B.C.**

**ValuMeds Pain Relief PM Pain Reliever and Nighttime Sleep Aid
Acetaminophen, Extra Strength**

Drug Facts

Active ingredients (in each caplet)

Acetaminophen USP, 500 mg
Diphenhydramine HCl USP, 25 mg

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

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 reach of children

Overdose warning: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 directed (see overdose warning)**

adults and children 12 years and over	<ul style="list-style-type: none">◦ take 2 caplets at bedtime◦ do not take more than 2 caplets of this product in 24 hours
children under 12 years	<ul style="list-style-type: none">◦ do not use

Other information

Drug Facts		Drug Facts (continued)					
Active ingredients (in each caplet)		Purpose					
Acetaminophen USP, 500 mg.....		Pain reliever					
Diphenhydramine HCl USP, 25 mg.....		Nighttime sleep aid					
Uses		<ul style="list-style-type: none"> do not drive a motor vehicle or operate machinery 					
temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness		Stop use and ask a doctor if					
Warnings		<ul style="list-style-type: none"> 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 					
<p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take</p> <ul style="list-style-type: none"> 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 <p>Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> skin reddening blisters rash <p>If a skin reaction occurs, stop use and seek medical help right away</p>		<p>These could be signs of a serious condition</p> <p>If pregnant or breast-feeding, ask a health professional before use</p> <p>Keep out of reach of children</p> <p>Overdose warning: 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.</p>					
Do not use		Directions					
<ul style="list-style-type: none"> 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 		<ul style="list-style-type: none"> do not take more than directed (see overdose warning) <table border="1"> <tr> <td>adults and children 12 years and over</td> <td> <ul style="list-style-type: none"> take 2 caplets at bedtime do not take more than 2 caplets of this product in 24 hours </td> </tr> <tr> <td>children under 12 years</td> <td> <ul style="list-style-type: none"> do not use </td> </tr> </table>		adults and children 12 years and over	<ul style="list-style-type: none"> take 2 caplets at bedtime do not take more than 2 caplets of this product in 24 hours 	children under 12 years	<ul style="list-style-type: none"> do not use
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children under 12 years	<ul style="list-style-type: none"> do not use 						
Ask a doctor before use if you have		Other information					
<ul style="list-style-type: none"> liver disease a breathing problem such as emphysema or chronic bronchitis trouble urinating due to an enlarged prostate gland glaucoma 		<ul style="list-style-type: none"> store between 20°-25°C (68°-77°F) see bottom of the label for expiration date and lot number 					
Ask a doctor or pharmacist before use if you are		Inactive ingredients					
<ul style="list-style-type: none"> taking the blood thinning drug warfarin taking sedatives or tranquilizers 		carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone k-30, pregelatinized starch, stearic acid, titanium dioxide					
When using this product		Questions or comments?					
<ul style="list-style-type: none"> drowsiness will occur avoid alcoholic drinks 		contact 1-908-242-6108 Mon- Fri 8:00 AM EST to 5:00 PM PST					

VALUMEDS PAIN RELIEF PM PAIN RELIEVER AND NIGHTTIME SLEEP AID ACETAMINOPHEN, EXTRA STRENGTH			
acetaminophen, diphenhydramine hydrochloride tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82725-1024
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	25 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE (Caplet)	Size	17mm
Flavor		Imprint Code	G651
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82725-1024-1	375 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	10/01/2024	

Labeler - Cabinet Health P.B.C. (117102391)