

**PAIN RELIEVER PM EXTRA STRENGTH- acetaminophen, diphenhydramine
hcl tablet, coated
CVS Pharmacy**

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.

Drug Facts

Active ingredients (in each gelta)

Acetaminophen 500 mg

Diphenhydramine HCl 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.
- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days

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 (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 gels at bedtime. Do not take more than 2 gels of this product in 24 hours.
- children under 12 years: do not use

Other information

- store at 20-25°C (68-86°F)
- avoid high humidity and excessive heat

Inactive ingredients

corn starch, croscarmellose sodium*, D&C red #27 aluminum lake, edible black ink, FD&C blue #1 aluminum lake, gelatin, glycerin, hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, purified water, silicon dioxide, sodium starch glycolate*, stearic acid, titanium dioxide

*contains one or more of these ingredients

Questions or comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

Compare to the active ingredients in Extra Strength Tylenol® PM†

EXTRA STRENGTH

Acetaminophen PM

ACETAMINOPHEN, 500 mg

DIPHENHYDRAMINE HCl, 25 mg

Pain reliever; Nighttime Sleep-aid

For Ages 12 & Over

Non-habit forming

GELTABS

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Extra Strength Tylenol® PM.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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Product Label

Compare to the active ingredients in Extra Strength Tylenol® PM†

GelTabs
NDC 69842-460-10

EXTRA STRENGTH
Acetaminophen PM
ACETAMINOPHEN, 500 mg
DIPHENHYDRAMINE HCl, 25 mg
Pain reliever; Nighttime sleep aid
For Ages 12 & Over
Non-habit forming

Actual Size
100 GELTABS

This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Extra Strength Tylenol® PM.
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CVS Quality
Lot No.: 0 50428 25073 0
Exp. Date:

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Drug Facts	Purposes
Active ingredients (in each geltab)	Pain reliever
Acetaminophen 500 mg	Nighttime sleep-aid
Diphenhydramine HCl 25 mg	
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: <ul style="list-style-type: none"> more than 4,000 mg of acetaminophen in 24 hours in 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: <ul style="list-style-type: none"> skin redness hives skin rash skin redness 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
Keep out of reach of children.	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

Drug Facts (continued)
When using this product
<ul style="list-style-type: none"> avoid alcohol do not drink or drive a motor vehicle or operate machinery
Stop use and ask a doctor if
<ul style="list-style-type: none"> sleeplessness persists continuously for more than 2 weeks. insomnia may be a symptom of a more serious underlying medical illness. new symptoms occur recurrent or severe swelling is present pain gets worse or lasts more than 10 days fever gets worse or lasts more than 3 days 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 (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
<ul style="list-style-type: none"> do not take more than directed (see Overdose warning) adults and children 12 years and over: take 2 geltabs at bedtime. Do not take more than 2 geltabs of this product in 24 hours. children under 12 years: do not use
Other information
<ul style="list-style-type: none"> store between 20°-25°C (68°-77°F) avoid high humidity and excessive heat
Inactive ingredients
corn starch, croscarmellose sodium, D&C red #27 aluminum lake, edible black ink, FD&C blue #1 aluminum lake, gelatin, glycerin, hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, purified water, silicon dioxide, sodium starch glycolate*, stearic acid, titanium dioxide *contains one or more of these ingredients
Questions or comments?
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CVS HEALTH Extra Strength Acetaminophen PM

PAIN RELIEVER PM EXTRA STRENGTH			
acetaminophen, diphenhydramine hcl tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-460
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
	STARCH, CORN (UNII: O8232NY3SJ)		
	D&C RED NO. 27 (UNII: 2LRS185U6K)		
	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
	GELATIN (UNII: 2G86QN327L)		
	GLYCERIN (UNII: PDC6A3C0OX)		
	HYPROMELLOSES (UNII: 3NXW29V3WO)		
	MALTODEXTRIN (UNII: 7CVR7L4A2D)		
	CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
	POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
	POVIDONE (UNII: FZ989GH94E)		

WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics

Color	white, blue	Score	no score
Shape	ROUND	Size	13mm
Flavor		Imprint Code	BP50
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-460-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2018	03/31/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/31/2018	03/31/2025

Labeler - CVS Pharmacy (062312574)