

**PAIN RELIEF 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.*

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**DRUG FACTS**

**Active ingredients (in each geltab)**

**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

**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

**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 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 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**

- store at room temperature 15°- 30° C (59°- 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\*, stearic acid, titanium dioxide  
\*contains one or more of these ingredients

**Questions or comments?**

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

**Principal Display Panel**

Compare to the active ingredients in extra strength **TYLENOL® PM \*\***

extra strength

**PAIN RELIEF PM**

**GELTABS**

**ACETAMINOPHEN 500 mg**

**DIPHENHYDRAMINE HCl 25 mg**

pain reliever/ nighttime sleep-aid

\*\*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol® PM

Non-habit forming

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION  
DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**Product Label**

## Pain Relief PM Geltabs

### PAIN RELIEF PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet, coated

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-360
<b>Route of Administration</b>	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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
WATER (UNII: 059QF0K00R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALUMINUM OXIDE (UNII: LM26O6933)	

#### Product Characteristics

<b>Color</b>	BLUE, WHITE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	BPI50
<b>Contains</b>			

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-360-15	1 in 1 BOX		

1		150 in 1 BOTTLE		
2	NDC:59779-360-24	1 in 1 BOX		
2		24 in 1 BOTTLE		
3	NDC:59779-360-50	1 in 1 BOX		
3		50 in 1 BOTTLE		
4	NDC:59779-360-10	1 in 1 BOX		
4		100 in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part338	07/08/2010	

**Labeler** - CVS Pharmacy (062312574)

**Registrant** - P and L Development of New York Corporation (800014821)

Revised: 12/2012

CVS Pharmacy