

**CVS EFFERVESCENT PAIN RELIEF PM- acetaminophen and diphenhydramine tablet**  
**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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**CVS Effervescent Pain Relief PM**

***Drug Facts***

**Active ingredient (in each tablet)**

Acetaminophen 500 mg

Diphenhydramine 25 mg

**Purpose**

Pain Reliever/fever reducer

Nighttime sleep-aid

**Uses**

temporary relief of occasional headaches and minor aches and pain with accompanying sleeplessness

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage can 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
- if you 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 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 beverages
- do not drive 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
- new symptoms occur
- 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 at 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)**
- dissolve tablets fully in 8 oz of water at room temperature
- do not chew or swallow tablet

Adults and children 12 years and over	<ul style="list-style-type: none"> <li>• take 2 tablets fully dissolved in 8 oz of water at room temperature at bedtime</li> <li>• do not take more than 2 tablets in 24 hours</li> </ul>
children under 12 years	do not use

**Other information**

- **each tablet contains:** potassium 156 mg; sodium 165 mg
- store between 20-25°C (68-77°F). Avoid excessive heat.
- do not use if individual pouch is torn or open

**Inactive ingredients**

anhydrous citric acid, FD&C red 40, flavor, polyethylene glycol, polysorbate, potassium bicarbonate, povidone, simethicone, sodium benzoate, sodium bicarbonate, sucralose

**Questions or comments**

**1-866-467-2748**

Distributed By: CVS Pharmacy, Inc.

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1-800-SHOP CVS

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

Tamper Evident: Do not use if individual pouch is torn or open. This is not a child resistant package. Keep out of reach of children.

**PRINCIPAL DISPLAY PANEL**

Effervescent Pain Relief PM

Extra Strength

Acetaminophen 500mg, Diphenhydramine HCl 25mg

Compare to the active ingredient in Extra Strength Tylenol® PM\*\*

Non-habit forming pain reliever/sleep aid

Aspirin & Ibuprofen free

For a restful night's sleep

No need to chew or swallow tablet

Berry flavor

16 Effervescent Tablets



## CVS EFFERVESCENT PAIN RELIEF PM

acetaminophen and diphenhydramine tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-577
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN)	
POVIDONES (UNII: FZ989GH94E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

SODIUM BENZOATE (UNII: OJ245FE5EU)

SODIUM BICARBONATE (UNII: 8MDF5V39QO)

SUCRALOSE (UNII: 96K6UQ3ZD4)

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	15mm
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	RP177
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-577-16	16 in 1 CARTON; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	02/02/2015	

**Labeler** - CVS Pharmacy (062312574)

Revised: 2/2015

CVS Pharmacy