

**DR SIMI PAIN RELIEVER PM- acetaminophen, diphenhydramine hydrochloride tablet, coated**  
**Farmacias De Similares TX LLC**

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**Extra Strength Pain Reliever PM**

***Drug Facts***

**Active ingredients (in each caplet)**

- Acetaminophen 500 mg
- Diphenhydramine HCl 25 mg

***Purpose***

- Pain reliever
- Nighttime sleep aid

***Uses***

Temporarily relief of occasional headaches and minor aches and pains with accompanying sleeplessness.

***Warnings***

***Warnings***

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take.

- More than 2 caplets in 24 hours, which is the maximum daily amount for this product.
- With other drugs containing acetaminophen.
- 3 or more alcoholic drinks everyday 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 not prescription). 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 your doctor or pharmacist before use if you are**

- Taking the blood thinning drug warfarin
- Taking sedative 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.**

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**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 use more than directed (see overdose warning).

**Directions**

Adults and children 12 years and over	<ul style="list-style-type: none"><li>• Take 2 caplets at bedtime.</li><li>• Do not take more than 2 caplets of this product in 24 hours.</li></ul>
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Children under 12 years	Do not use
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**Other information**

- Store at 25 °C (77°F) excursions permitted between 15-30°C (59-86°F)
- Read all product information before using.
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**Inactive ingredients**

FD&C Blue No. 1, FD&C Blue No. 2, Hypromellose, Magnesium stearate, Microcrystalline cellulose, Polyethylene glycol, Povidone, Pregelatinized starch, Purified water, Stearic Acid, Titanium dioxide.

**Questions or comments?**

(855)-280-1079

**Distributed by: FARMACIAS DE SIMILARES TX, LLC**

800 Brazos St Ste 260, Austin, TX,  
78701, USA.

customerservice@drsimi.com

www.drsimi.com

LOT:

EXP:

**PEEL BACK for more DRUG FACTS**

DR SIMI

NDC 85786-101-90

Extra Strength

Pain Reliever PM

Acetaminophen 500 mg

*Pain Reliever*

Diphenhydramine HCl 25 mg

*Nighttime Sleep Aid*

*100 Caplets*

Aspirin Free

Non-Habit Forming

For Adults



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Temporarily relief of occasional headaches and minor aches and pains with accompanying sleeplessness.

**Warnings**  
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- With other drugs containing acetaminophen.
- 3 or more alcoholic drinks every day while using this product.

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**Do not use** ■ With any other drug containing acetaminophen (prescription or not prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.  
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 ■ In children under 12 years of age.  
 ■ If you have ever had an allergic reaction to this product or any of its ingredients.

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LOT: 8 50070 04881 1  
EXP:

**PEEL BACK HERE TO REVEAL FACTS**

Reseal Area

**Drug Facts (continued)**

**Ask a doctor before use if you have** ■ Liver disease.  
 ■ A breathing problem such as emphysema or chronic bronchitis.  
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**Questions or comments?** (855)-280-1079

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DR SIMI PAIN RELIEVER PM			
acetaminophen, diphenhydramine hydrochloride tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85786-101
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg	
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg	
Inactive Ingredients			
Ingredient Name	Strength		
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)			
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)			
<b>WATER</b> (UNII: 059QF0KO0R)			
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)			

<b>STEARIC ACID</b> (UNII: 4ELV7Z 65AP)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I3O)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	APM
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85786-101-90	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/15/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/11/2025	

### Labeler - Farmacias De Similares TX LLC (119489934)

### Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd		863182240	manufacture(85786-101) , analysis(85786-101) , pack(85786-101) , label(85786-101)

Revised: 8/2025

Farmacias De Similares TX LLC