

**EXTRA STRENGTH PAIN RELIEF PM- acetaminophen and diphenhydramine hydrochloride tablet**  
**SPIRIT PHARMACEUTICALS LLC**

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**Pain Relief PM (Pain Reliever & Nighttime Sleep Aid)**

***Drug Facts***

***Active ingredients (in each caplet)***

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

***Purpose***

Pain reliever

Nighttime sleep aid

***Uses***

For the 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 with this product 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 you are 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 other drug acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any 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
- breathing problems such as emphysema or chronic bronchitis
- trouble urinating due to an enlargement of the 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 a serious underlying medical illness
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

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**

Taking more than the directed dose (overdose) may cause liver damage. 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"><li>• take 2 caplets at bedtime</li><li>• do not take more than 2 caplets of this product in 24 hours</li></ul>
children under 12 years	do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

**Other information**

- **each caplet contains:** magnesium 0.05 mg
- store between 20°-25°C (68°-77°F)

**Inactive ingredients**

FD&C blue # 1, FD&C blue # 2, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol-400, povidone k-30, pregelatinized starch, purified water, stearic acid, titanium dioxide

**Questions or comments?**

**1-888-333-9792**

**PRINCIPAL DISPLAY PANEL**

Extra Strength  
Pain Relief PM

Acetaminophen 500 mg  
Diphenhydramine HCl 25 mg  
Pain Reliever/Nighttime Sleep-Aid

100 caplets



<b>EXTRA STRENGTH PAIN RELIEF PM</b>			
acetaminophen and diphenhydramine hydrochloride tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-4095
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	500 mg

**DIPHENHYDRAMINE HYDROCHLORIDE** (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>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL (Capsule shaped, biconvex)	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	S525
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4095-1	100 in 1 PACKAGE; Type 0: Not a Combination Product	07/02/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/02/2020	

**Labeler** - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 12/2024

SPIRIT PHARMACEUTICALS LLC