

**PAIN RELIEVER AND SLEEP AID- acetaminophen, and diphenhydramine hydrochloride tablet, film coated**  
**Spirit Pharmaceuticals LLC**

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**Pain Reliever and Sleep Aid**

***Drug Facts***

***Active Ingredient (in each tablet)***

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 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 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 • 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. (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)

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adults & children 12 years &  
over

- take 2 tablets at bedtime
- do not take more than 2 tablets of this product in 24 hours

children under 12 years

do not use

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**Other information**

- store between 20–25°C (68–77°F)

***Inactive ingredients***

FD&C Blue No. 1, FD&C Blue No. 2, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid, titanium dioxide

***Questions or comments?***

**1-888-333-9792**

**Distributed by:**

Cabinet Health P.B.C.

**Pouch**

PACKAGE NOT CHILD-RESISTANT



CABINET:

## Pain Reliever & Sleep Aid

Compare to the active ingredients in:  
Tylenol® PM\*

**Active ingredients:**  
ACETAMINOPHEN 500 MG  
DIPHENHYDRAMINE HCl 25 MG

**Relieves:**  
Headache  
Aches and Pains  
Sleeplessness

### COMPOSTABLE REFILL POUCH

Includes:

30 x  Caplets

1 x Magnetic Label

1 x Drug Facts Booklet

Certified



Corporation

CABINET: The Sustainable Healthcare Co.™

## PAIN RELIEVER AND SLEEP AID

acetaminophen, and diphenhydramine hydrochloride tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-4185
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<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

<b>Ingredient Name</b>	<b>Strength</b>
<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, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<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>	CAPSULE	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	S26
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:68210-4185-3	30 in 1 POUCH; Type 0: Not a Combination Product	11/22/2021	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M013	11/22/2021	

**Labeler** - Spirit Pharmaceuticals LLC (179621011)

