# 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)

adults & children 12 years & over	<ul> <li>take 2 tablets at bedtime</li> <li>do not take more than 2 tablets of this product in 24 hours</li> </ul>
children under 12 years	do not use

#### Other information

• store between 20-25°C (68-77°F)

# Inactive ingredients

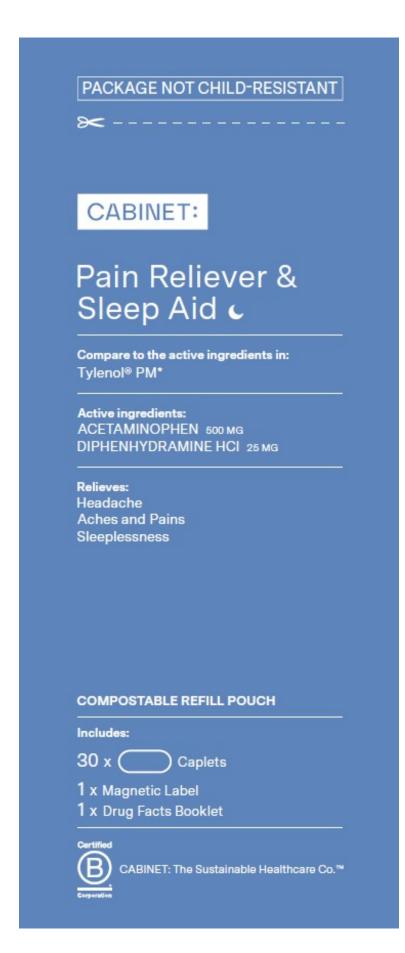
FD&C Blue No. 1, FD&C Blue No. 2, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments? 1-888-333-9792

# Distributed by:

Cabinet Health P.B.C.

## **Pouch**



# **PAIN RELIEVER AND SLEEP AID**

acetaminophen, and diphenhydramine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4185
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg	
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg	

Inactive Ingredients				
Ingredient Name	Strength			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE (UNII: FZ989GH94E)				
STARCH, CORN (UNII: O8232NY3SJ)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				

Product Characteristics				
Color	blue	Score	no score	
Shape	CAPSULE	Size	18mm	
Flavor		Imprint Code	S26	
Contains				

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

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

Revised: 12/2023 Spirit Pharmaceuticals LLC