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

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	• 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

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

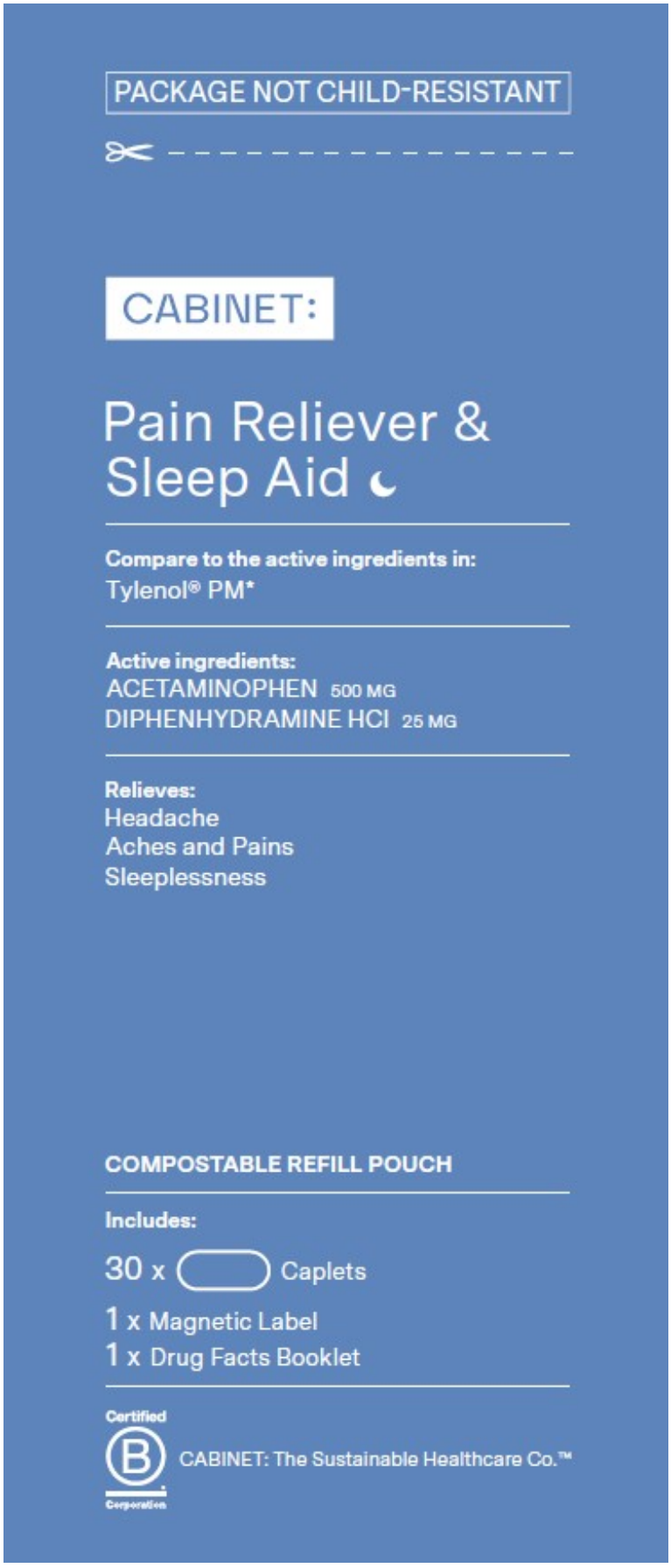
Questions or comments?

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: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (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: 3WQ0SDW1A)	
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
1	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	

Labeler - Spirit Pharmaceuticals LLC (179621011)