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

Extra Sterength Pain Relief PM

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	• take 2 caplets at bedtime • do not take more than 2 caplets of this product in 24 hours
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 - Pain Reliever
Diphenhydramine 25 mg - Nighttime Sleep-Aid

Non-habit forming

24 Softgels

EXTRA STRENGTH PAIN RELIEF PM
acetaminophen and diphenhydramine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-4145
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 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	S525
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4145-2	1 in 1 CARTON	04/28/2021	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	04/28/2021	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

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