

ASSURED HEADACHE PM (ASPIRIN FREE)- acetaminophen and diphenhydramine citrate tablet, coated
Spirit Pharmaceutical LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Headache PM (Aspirin Free)

Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 500 mg	Pain reliever
Diphenhydramine citrate 38 mg	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 if you take

- more than 2 caplets in 24 hours, which is the maximum daily amount
- 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 or general allergic reaction occurs, stop use and seek medical help right away.

Do not use

- if you are allergic to acetaminophen
- with any 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

Ask a doctor before use if you have

- liver disease
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- avoid alcoholic drinks
- drowsiness may occur
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- any new symptoms occur
- sleeplessness lasts continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.
- pain gets worse or lasts more than 10 days
- painful area is red or swollen
- fever gets worse or lasts more than 3 days

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. 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 use more than directed**
- do not use in children under 12 years of age
- adults and children 12 years of age and over: take 2 caplets at bedtime, if needed, or as directed by a doctor

Other information

- store at controlled room temperature 20°-25°C (68°-77°F)
- read all product information before using. Keep this box for important information.

Inactive ingredients

colloidal silicon dioxide, FD&C Blue # 1, FD&C blue #2, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized corn starch, stearic acid, titanium dioxide

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

Headache PM
Acetaminophen 500 mg - Pain Reliever
Diphenhydramine Citrate 38 mg - Nighttime Sleep-aid

Aspirin Free

Non habit forming

20 Caplets



ASSURED HEADACHE PM (ASPIRIN FREE)

acetaminophen and diphenhydramine citrate tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4135
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE CITRATE (UNII: 4OD433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE CITRATE	38 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
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:68210-4135-2	1 in 1 CARTON	04/28/2021	
1		20 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 not final	part343	04/28/2021	

Labeler - Spirit Pharmaceutical LLC (179621011)

Revised: 11/2021

Spirit Pharmaceutical LLC