ACETAMINOPHEN DIPHENHYDRAMINE HCL- acetaminophen diphenhydramine hcl capsule
FREDS, INC

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.

EXTRA STRENGTH
PAIN RELIEF PM
Pain Reliever/Nighttime Sleep Aid
Acetaminophen, USP 500 mg each/
Diphenhydramine HCl 25 mg each

Active ingredients

(in each caplet)

Acetaminophen, USP 500 mg
Diphenhydramine HCl 25 mg

Purposes

Pain reliever
Nighttime sleep aid

Uses

temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

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 reaction. Symptoms may include:
■ skin reddening
■ blisters
■ rash
If a skin reaction occurs, stop use and seek medical help right away.

Do not use

■ 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
■ 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

■ 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 serious underlying medical illness.
■ pain gets worse or lasts 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 the reach of children

Overdose warning

Taking more than the recommended 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

Other information

■ store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature.
■ see end panel for lot number and expiration date

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, microcrystalline cellulose, pregelatinized starch, polysorbate 80, polyethylene glycol, povidone k-30, stearic acid, titanium dioxide

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Questions or comments?

cal l **1-877-770-3183** Mon-Fri 9:00 AM to 4:30 PM EST

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Acetaminophen, USP 500 mg each/
Diphenhydramine HCl 25 mg each
Asprin Free
Non Habit-Forming
100 CAPLETS+
(+ Capsule-Shaped Tablets)

ACETAMINOPHEN DIPHENHYDRAMINE HCL

acetaminophen diphenhydramine hcl capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55315-990
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**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE K30 (UNII: U725QWY32X)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	blue	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	G651
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55315-990-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/17/2017	

Labeler - FREDS, INC (005866116)

Revised: 7/2017 FREDS, INC