

**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 ingredient

Active ingredient Purpose
(in each gelcap)
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

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

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.

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 gelcaps at bedtime
 - do not take more than 2 gelcaps 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

colloidal silicon dioxide, croscarmellose sodium, FD&C blue #2, FD&C red #40, FD&C Yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, isopropyl alcohol, microcrystalline cellulose, n-butyl alcohol, povidone, pregelatinized starch, propylene glycol, shellac glaze, stearic acid, titanium dioxide, triacetin.

Questions or comments?

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

EXTRA STRENGTH

PAIN RELIEF PM

Pain Reliever/Nighttime Sleep Aid

Acetaminophen, USP 500 mg each/

Diphenhydramine HCl 25 mg each

Aspirin Free

Non-Habit Forming

24 GELCAPS



ACETAMINOPHEN DIPHENHYDRAMINE HCL			
acetaminophen diphenhydramine hcl capsule			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-988
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
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	gray (with dark blue opaque and light blue opaque hard gelatin shells)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	G3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-988-24	24 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	

