EXTRA STRENGTH NIGHT TIME PAIN MEDICINE- acetaminophen, diphenhydramine hcl tablet, coated
Geri-Care Pharmaceutical Corp

GC 224B (324)

Active Ingredients

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purposes

Pain Reliever

Sleep aid

Uses

for the temporary relief of occasional headaches and minor ache and pains along 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 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 • glaucoma • difficulty urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking • the blood thinning drug warfarin

• sedatives or tranquilizers

When using this product • drowsiness will occur • do not drive a motor vehicle or operate machinery after use • avoid alcoholic drinks

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 that 10 days • fever gets worse or lasts more than 3 days • new symptoms occur • redness or swelling is present.These may 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 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 at controlled room temperature 20-25 °C (68-77° F)

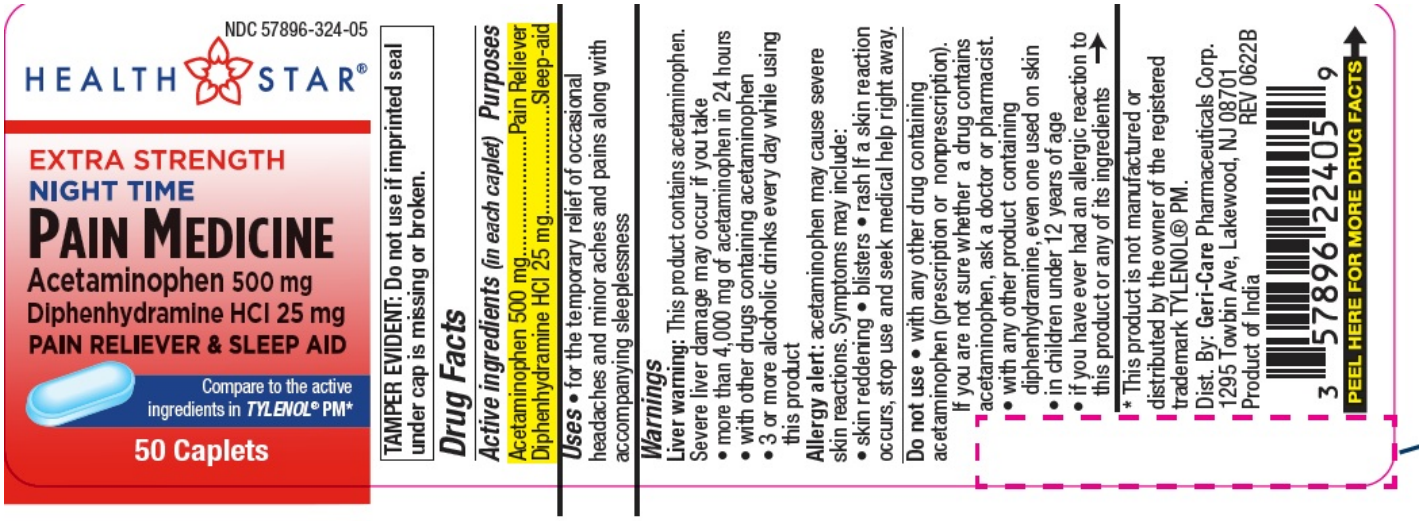
Inactive ingredients

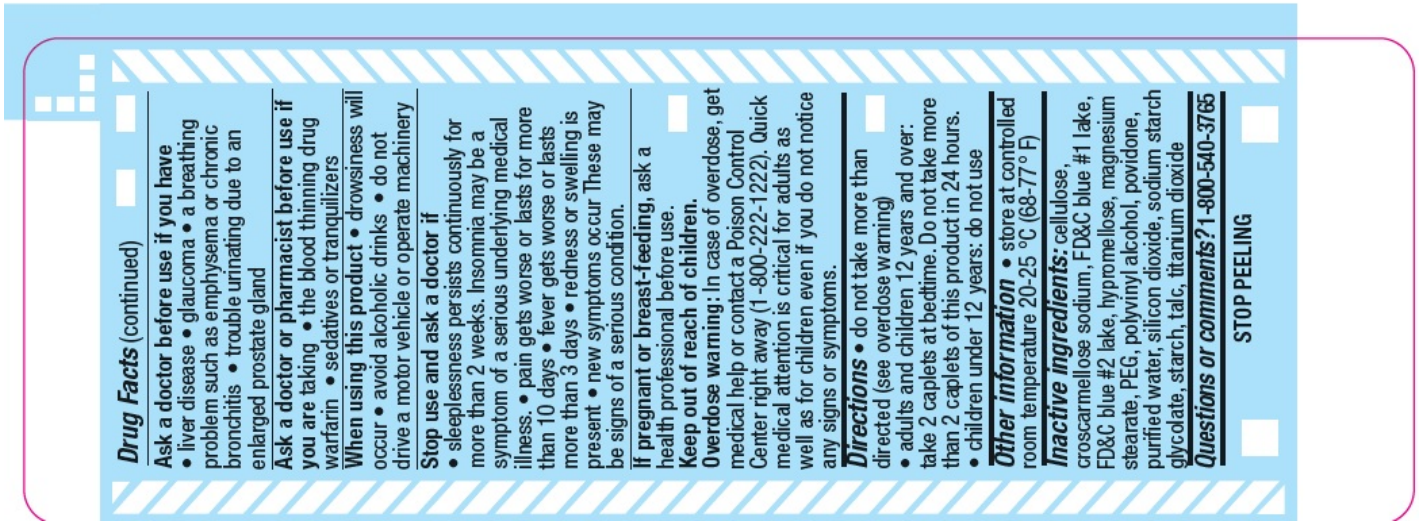
cellulose, croscarmellose sodium, FD&C blue #1 lake, FD&C blue #2 lake, hypromellose, magnesium stearate, PEG, polyvinyl alcohol, povidone, purified water, silicon dioxide, sodium starch glycolate, starch, talc, titanium dioxide

Questions or comments?

1-800-540-3765

package Label





EXTRA STRENGTH NIGHT TIME PAIN MEDICINE

acetaminophen, diphenhydramine hcl tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57896-324
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**
TALC (UNII: 7SEV7J4R1U)	

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POVIDONE (UNII: FZ989GH94E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
WATER (UNII: 059QF0KO0R)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics

Color	blue	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	P525
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-324-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2022	
2	NDC:57896-324-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	06/01/2022	02/28/2026

Labeler - Geri-Care Pharmaceutical Corp (611196254)

Registrant - Geri-Care Pharmaceutical Corp (611196254)

Revised: 11/2024 Geri-Care Pharmaceutical Corp