ACETAMINOPHEN DIPHENHYDRAMINE HCL- acetaminophen diphenhydramine hcl tablet
Chain Drug Consortium,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.

Acetaminophen 500 mg / Diphenhydramine HCl 25mg Tablets (Caplets)

Active ingredient

(in each caplet)

Acetaminophen, USP 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever

Nighttime sleep aid

Uses

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 4,000 mg of acetaminophen in 24 hours

■ with other drugs containing acetaminophen

■ 3 or more alcoholic drinks every day while using this product

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 this product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

Other information

■ store between 20°-25°C (68°-77°F)

■ **do not use if carton is opened, or neck wrap or foil inner seal broken or mising**

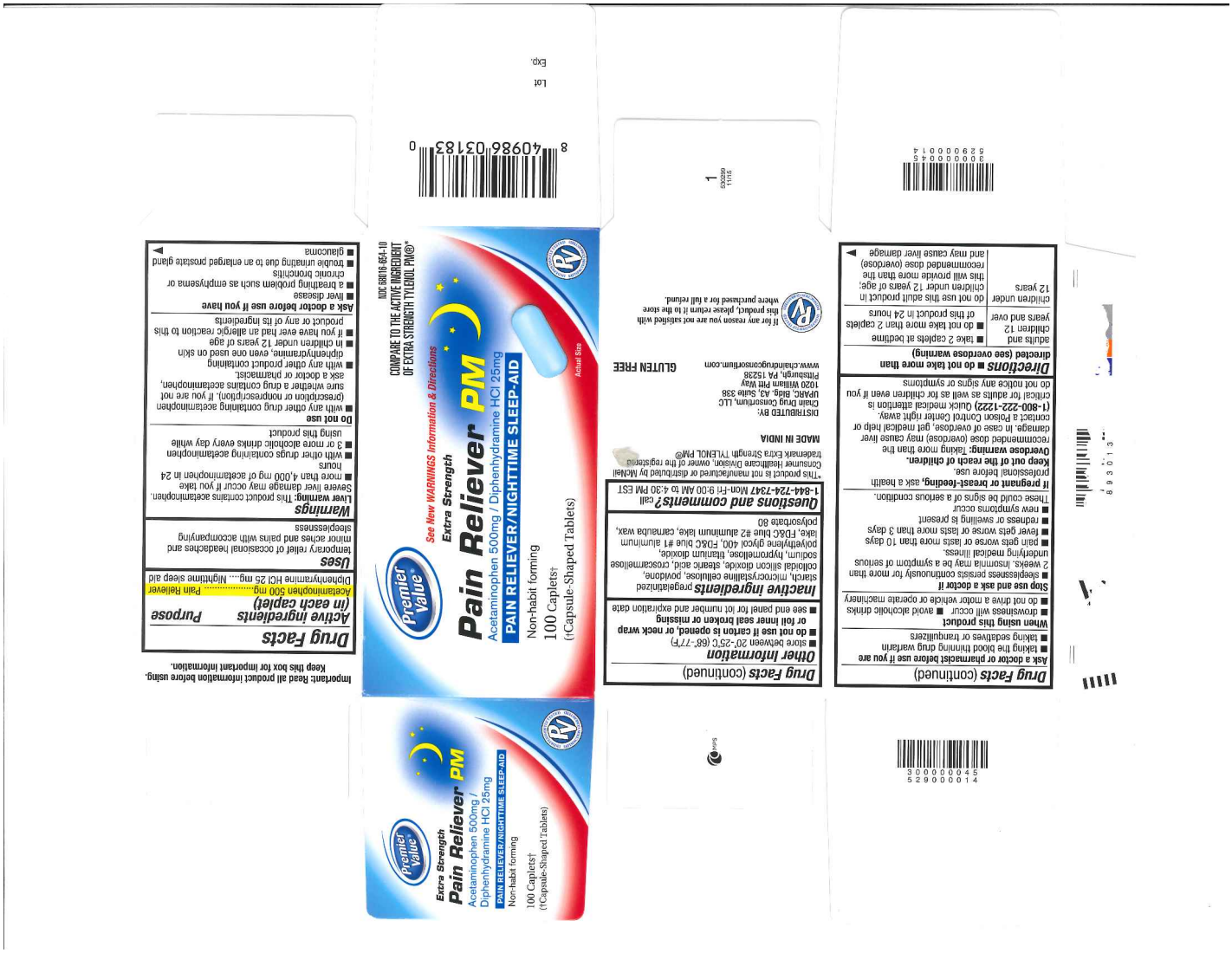
■ see end panel for lot number and expiration date

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 400, povidone, stearic acid, titanium dioxide

Questions and comments?

call **1-844-724-7347** Mon-Fri 9:00 AM to 4:30 PM EST



ACETAMINOPHEN DIPHENHYDRAMINE HCL

acetaminophen diphenhydramine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-654
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE (UNII: 8GTS82S83M) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics			
Color	blue	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	G651
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-654-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	02/25/2016	
2	NDC:68016-654-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/25/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	02/25/2016	

Labeler - Chain Drug Consortium,LLC (101668460)

Revised: 2/2017 Chain Drug Consortium,LLC