ACETAMINOPHEN AND DIPHENHYDRAMINE HCL - acetaminophen and diphenhydramine hcl tablet
Carilion Materials Management

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 and Diphenhydramine HCl Captabs

Active Ingrdient

(in each captab)

PURPOSE

Pain Reliever/Sleep Aid

Uses

Temporarily relieves 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 8 captabs in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday 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 drug 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
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are.

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

When using this product

- marked drowsiness will occur
- avoid alcoholic drinks
- alcohol, sedatives and tranquilizers may increase drowsiness
- do not drive motor vehicle or operate machinery

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present

- any new symptoms appear
- sleeplessness lasts more than 2 weeks. Insomnia may be a sign of serious underlying medical illness.

If pregnant or breast feeding, ask a health professional before use.

Keep out of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

Directions

adults and children 12 years or over:
- take 2 captabs at bedtine if needed
- do not take more than directed

childrens under 12 years do not use

Other Information

Store at room temperature 15°-30°C (59°-86°F)

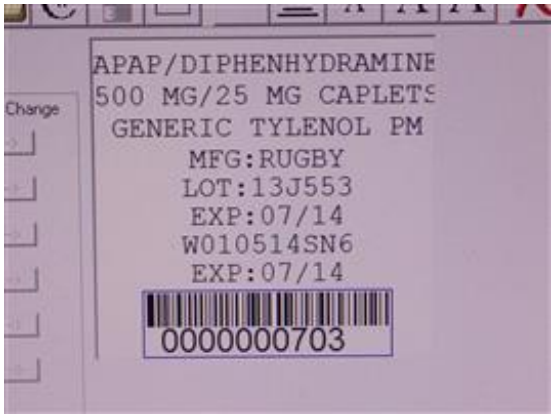
Inactive Ingredients

Croscarmellose sodium, FD&C blue #1, hypromellose, microcrystalline cellulose, polyethylene glycol 400, povidone, pregelatinized corn starch, silicon dioxide, stearic acid, titanium dioxide.

QUESTIONS

Call 1-800-645-2158, 9 am – 5 pm ET, Monday – Friday.

Acetaminophen/Diphenhydramine



ACETAMINOPHEN AND DIPHENHYDRAMINE HCL

acetaminophen and diphenhydramine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68151-0703(NDC:0536-3479)
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (light blue)	**Score**	no score
Shape	CAPSULE	**Size**	17mm
Flavor		**Imprint Code**	AP;133
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68151-0703-0	1 in 1 PACKAGE; Type 0: Not a Combination Product	10/06/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	10/06/2010	

Labeler - Carilion Materials Management (079239644)

Establishment

Name	Address	ID/FEI	Business Operations
Carilion Materials Management		079239644	REPACK(68151-0703)