ALLERGY- diphenhydramine hydrochloride tablet, film coated Kroger Company

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.

160R KROGER 41226 160 Diphenhydramine Hydrochloride Tablets

DRUG FACTS

Diphenhydramine HCl 25 mg

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- itchy, watery eyes
- sneezing
- itchy nose or throat

temporarily relieves these symptoms due to the common cold:

- runny nose
- sneezing

Warnings

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- 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 sedatives or tranquilizers

When using this product

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- excitability may occur, especially in children
- be careful when driving a motor vehicle or operating machinery

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

Keep out of reach ot children. In case of overdose, get medical help or contact a Poison Control Center right away(I-800-222-1222).

Directions

- take every 4 to 6 hours
- do not take more than 6 doses in 24 hours

adults and children 12 years of age and over 1 to 2 caplets children 6 to under 12 years of age 1 caplet children under 6 years of age do not use this product in children under 6 years of age

OTHER INFORMATION

Other information

- each caplet contains: calcium 25 mg
- protect from light
- store at 25°C (77°F) excursions permitted 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C red #27 aluminum lake, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG) 400, polysorbate 80, titanium dioxide

Questions or comments?

1-800-632-6900

Allergy 400ct Carton

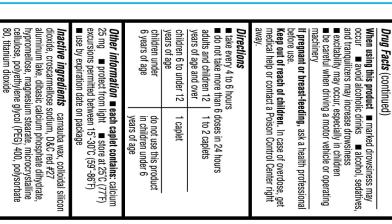


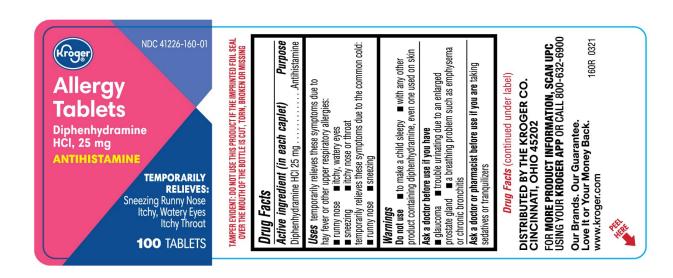
Allergy 400ct Label



Allergy 100ct Carton

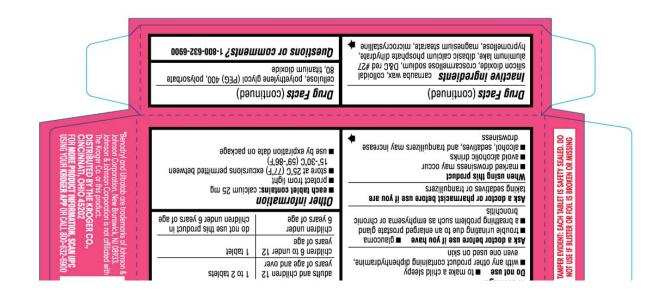






Questions or comments? 1-800-632-6900

Allergy 24ct Carton





ALLERGY

diphenhydramine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-160
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg	

Inactive Ingredients		
Ingredient Name	Strength	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
D&C RED NO. 27 (UNII: 2LRS185U6K)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics			
Color	pink	Score	no score
Shape	CAPSULE	Size	11mm
Flavor		Imprint Code	T;061
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41226- 160-42	1 in 1 CARTON	05/11/2021	
1		12 in 1 BLISTER PACK		
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41226- 160-40	1 in 1 CARTON	05/11/2021	
2		400 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:41226- 160-01	1 in 1 CARTON	05/11/2021	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/11/2021	

Labeler - Kroger Company (006999528)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment				
Na me	Address	ID/FEI	Business Operations	
TIME CAP LABORATORIES, INC.		037052099	manufacture(41226-160)	

Revised: 4/2021 Kroger Company