

**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.*

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**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 of children.** In case of overdose, get medical help or contact a Poison Control Center right away(1-800-222-1222).

**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



NDC 41226-160-40

# Allergy Tablets

Diphenhydramine HCl, 25 mg

**ANTIHISTAMINE**

**TEMPORARILY RELIEVES:**  
Sneezing Runny Nose  
Itchy, Watery Eyes  
Itchy Throat

**400 TABLETS**

**TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING**

**RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION**

**Drug Facts**

**Active ingredient (in each tablet)**

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**

■ 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 of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

**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 tablets

■ children 6 to under 12 years of age: 1 tablet

■ children under 6 years of age: do not use this product in children under 6 years of age

**Other information**

■ each tablet contains calcium 25 mg

■ protect from light ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ use by expiration date on package

**Questions or comments?** 1-800-632-6900

**DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202**

**FOR MORE PRODUCT INFORMATION, SCAN UPC**

**USING YOUR KROGER APP OR CALL 800-632-6900**

**Our Brands. Our Guarantee. Love It or Your Money Back.**

www.kroger.com

LOT #:

EXP. DATE:

160R 0321

Allergy 100ct Carton

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

**Drug Facts**

**Active ingredient (in each tablet)**  
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**

**Drug Facts (continued)**

**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 of children.** In case of overdose, get medical help or contact Poison Control Center right away (1-800-222-1222).

**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 tablets  
children 6 to under 12 years of age 1 tablet  
children under 6 years of age do not use this product in children under 6 years of age

**Other information**

■ each tablet contains: calcium 25 mg  
■ protect from light  
■ store at 25°C (77°F); excursions permitted

160R 0321  
PLEASE RECYCLE  
80% SIZE  
12-digit UPC-A  
(non-suppressed)  
For Position Only  
0 41260 01234 1  
LOT NO.  
EXP.

**Drug Facts (continued)**

between 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, poly sorbate 80, titanium dioxide  
**Questions or comments?**  
1-800-632-6900

**WARNING: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING**

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NDC 41226-160-01

COMPARE TO the active ingredient of **BENADRYL® ALLERGY ULTRATAB™ TABLETS** \*See top panel



**Allergy Tablets**

Diphenhydramine HCl,  
25 mg

**ANTIHISTAMINE**



actual size

**TEMPORARILY RELIEVES:**  
Sneezing Runny Nose  
Itchy, Watery Eyes  
Itchy Throat

**100 TABLETS**

E3144R

Allergy 100ct label



NDC 41226-160-01

# Allergy Tablets

Diphenhydramine HCl, 25 mg

**ANTIHISTAMINE**

**TEMPORARILY RELIEVES:**  
Sneezing Runny Nose  
Itchy, Watery Eyes  
Itchy Throat

**100 TABLETS**

**TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING**

### Drug Facts

**Active ingredient (in each caplet)** Purpose  
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

*Drug Facts (continued under label)*

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CINCINNATI, OHIO 45202**

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160R 0321



Allergy 24ct Carton

**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 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

**Other Information**

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

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

**Drug Facts (continued)**

**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**

**TAMPER EVIDENT: EACH TABLET IS SAFETY SEALED. DO NOT USE IF BULSTER OR FOIL IS BROKEN OR MISSING**

\*Brand/ and Ultrab are trademarks of Johnson & Johnson Corporation, New Brunswick, NJ 08933. The Kroger Co. or this product. CINCINNATI, OHIO 45202. FOR MORE PRODUCT INFORMATION, SCAN UPC USING YOUR KROGER APP OR CALL 800-632-6900

**Drug Facts (continued)**

**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 of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

■ take every 4 to 6 hours	■ do not take more than 6 doses in 24 hours
■ do not take more than 6 doses in 24 hours	adults and children 12 years of age and over
children 6 to under 12 years of age	1 to 2 caplets
children under 6 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** ■ each caplet contains: calcium 25 mg ■ protect from light ■ store at 25°C (77°F) ■ excursions permitted between 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

diphenhydramine hydrochloride tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41226-160
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	T;061
<b>Contains</b>			

## 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**

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

Revised: 4/2021

Kroger Company