## ALLERGY RELIEF- diphenhydramine hydrochloride tablet, film coated DOLGENCORP, 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.

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#### 160R 55910 959 Dollar General DIPHENHYDRAMINE HYDROCHLORIDE 24CT

#### **DRUG FACTS**

**Active Ingredient** (in each tablet)

Diphenhydramine Hydrochloride 25mg

## **Purpose**

**Antihistamine** 

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

- runny nose
- sneezing
- itchy, watery eyes
- 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.

#### **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

#### 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

**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? call 1-888-309-9030





### **ALLERGY RELIEF**

diphenhydramine hydrochloride tablet, film coated

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:55910-959 Route of Administration 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		
CARNAUBA WAX (UNII: R12CBM0EIZ)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	pink	Score	no score
Shape	CAPSULE	Size	11mm
Flavor		Imprint Code	T061
Contains			

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
<b>1</b> NDC:55910- 959-24	1 in 1 CARTON	07/24/2021			
1	24 in 1 BLISTER PACK; Type 0: Not a Combination Product				

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/24/2021	

## Labeler - DOLGENCORP, LLC (068331990)

## Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
TIME CAP LABORATORIES, INC.		037052099	manufacture(55910-959)	

Revised: 4/2021 DOLGENCORP, LLC