

**ALLERGY RELIEF- diphenhydramine hydrochloride tablet, film coated**  
**TIME CAP LABORATORIES, INC**

-----  
**160R timely 49483-061 Diphenhydramine HCl 25mg**

**DRUG FACTS**

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

Diphenhydramine HCl 25 mg

***Purpose***

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 Centre (1-800-222-1222) 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 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

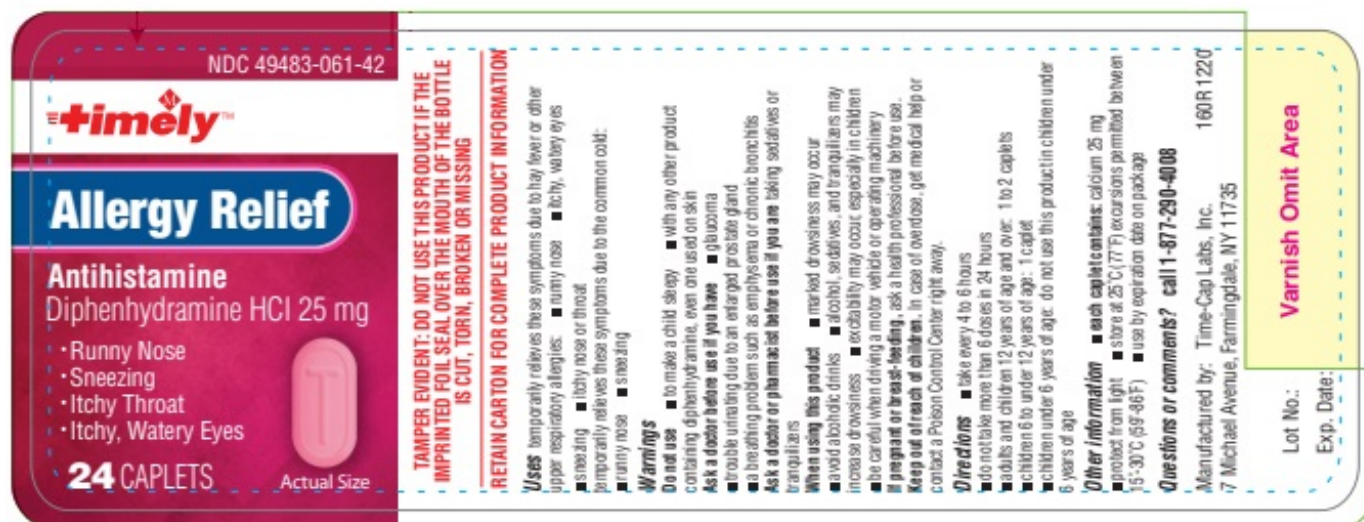
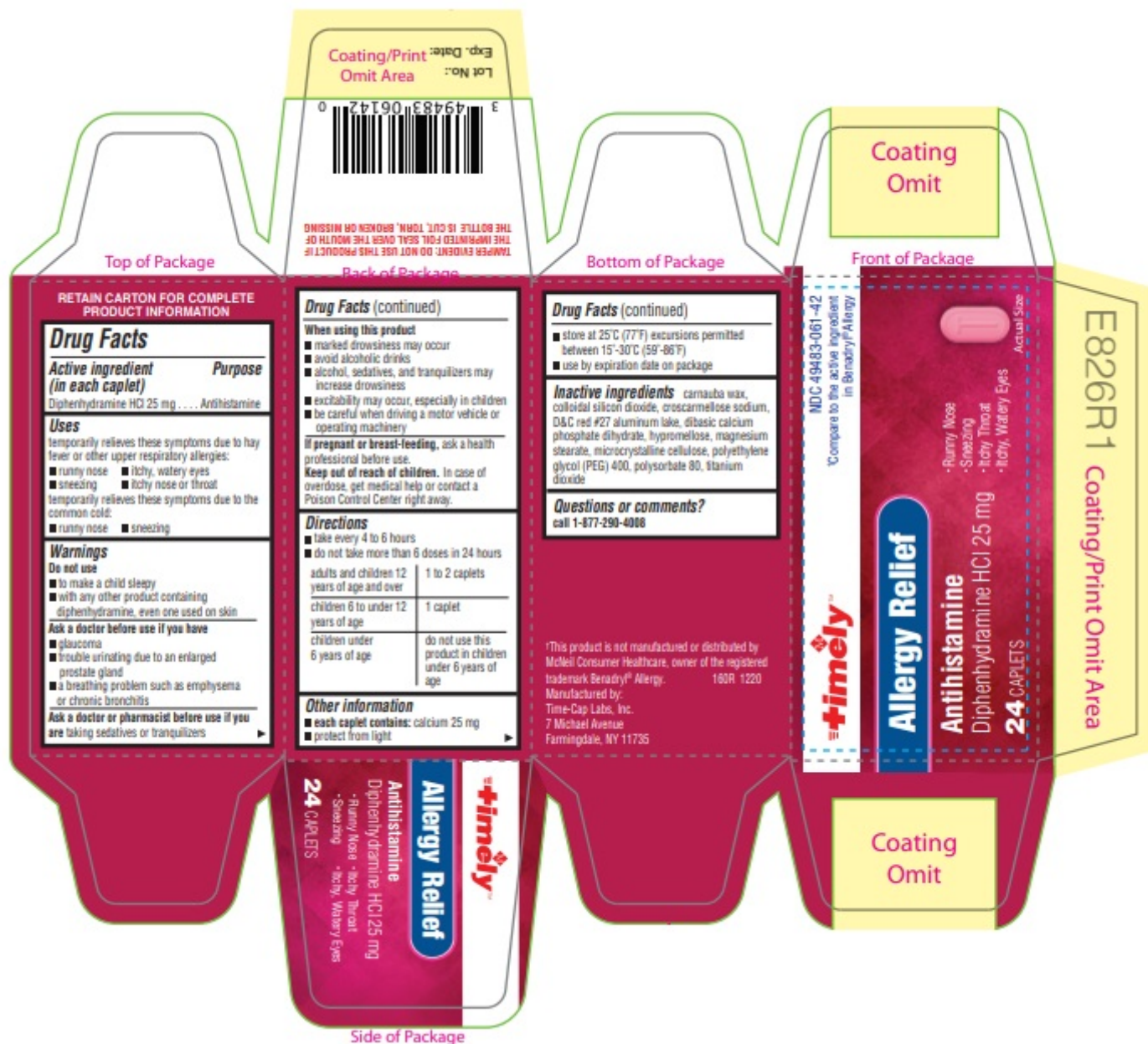
## **OTHER INFORMATION**

### ***Other information***

- **each caplet contains:** calcium 25 mg
- protect from light
- store at 25°C (77°F) excursions permitted 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 no 27 aluminum lake, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol(PEG) 400, polysorbate 80, titanium dioxide

***Questions or comments?call 1-877-290-4008***









<b>D&amp;C RED NO. 27 ALUMINUM LAKE</b> (UNII: ZK64F7XSTX)	
<b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I3O)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<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>	T061
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-061-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/17/2018	
2	NDC:49483-061-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/17/2018	
3	NDC:49483-061-62	650 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2012	
4	NDC:49483-061-42	1 in 1 CARTON	07/30/2021	
4		24 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:49483-061-65	365 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/01/2012	

**Labeler** - TIME CAP LABORATORIES, INC (037052099)

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

## Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC		037052099	manufacture(49483-061)

## Establishment

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

MARKSANS PHARMA LIMITED		677604129	manufacture(49483-061)
-------------------------	--	-----------	------------------------

Revised: 6/2025

TIME CAP LABORATORIES, INC