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 HCI 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

Ouestions or comments?call 1-877-290-4008



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

marked drowsiness may occur
 avoid alcoholic drinks
 alcohol, sedatives, and tranquilizers may

excitability may occur, especially in children
 be careful when driving a motor vehicle or

If pregnant or breast-feeding, ask a health

professional before use. Keep out of reach of children. In case of

Drug Facts (continued)

When using this product

increase drowsiness

Bottom of Package

Drug Facts (continued)

- store at 25°C (77°F) excursions permitted between 15'-30°C (59'-86°F)
- use by expiration date on package

Inactive ingredients camauba 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, Stanium dioxide

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

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registers Manufactured by: Time-Cap Labs, Inc

Farmingdale, NY 11735

Allergy Relief

Coating Omit

Front of Package

Compare to the active ingredient in Benadry PATergy

*+imely

NDC 49483-061-42

Antihistamine

Diphenhydramine HCI 25 mg

Coating/Print Omit Area

Coating Omit

Top of Package

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredient (in each caplet)

Purnose

Uses

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

- runny nose itchy, watery eyes steezing itchy nose or throat
- temporarily relieves these symptoms due to the
- 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

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 | 1 to 2 caplets years of age and over children 6 to under 12 years of age product in children under 6 years of 6 years of age

Other information

■ each caplet contains: calcium 25 mg ■ protect from light

age

Allergy Relief Jiphenhydramine HC125 i

Side of Package

NDC 49483-061-42



Allergy Relief

Antihistamine Diphenhydramine HCI 25 mg

- Runny Nose
- Sneezing
- Itchy Throat · Itchy, Watery Eyes
- 24 CAPLETS



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

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

IMPRINTED

temporarily relieves these symptoms due to hay fever or other

respiratory allergies: a rumy nose allochy, watery eyes semporarily relieves these symptoms due to the common cold itchy nose or throat FUNDA NOSE Sneezing Uses 100dr

Sheezing

product Warnings

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 a breathing problem such as emphysema or chronic bronchitis
 Ask a doctor or pharmacial before use iff you are taking sociatives or rangulizers

■avoid abothdic drinks ■ aloohbil, seddives, and tranquitians may increase or developers. ■ excelobility may occur especially in children also careful when driving a motor vehicle or operating machinery. If a gegand or treast-feeding, sex, a health professional before uso. Keep and of reasth of children, in case of overdose, get medical help or When using this product marked drowsiness may occur

contact a Poison Control Center right away. Directions atake every 4 to 6 hours

adults and children 12 years of age and over. 1 to 2 caplets ■do nottake more than 6 doses in 24 hours

■children under 6 years of age: do not use this productin children under achildren 6 to under 12 years of age:

■ store at 25 °C (77°F) excursions permitted ■ use by expiration date on package Other information = each caplet contains: calcium 25 protect from light years of age

Questions or comments? call 1-877-290-4008 Manufactured by: 5-30°C (59°-86°F)

No.: ĕ

Varnish Omit Area

Farmingdale, NY 11735 Time-Cap Labs, Inc.

Michael Avenue,

160R 1220

Date Exp. TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROXEN OR MISSING

Exp. Date:

Compare to the active ingredient in Benadryl*Allergy NDC 49483-061-01

Varnish Omit

Bottom of Package

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, polysorbate 80, titanium dioxide

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

¹This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Benadryl[®] Allergy 160R 1220

Manufactured by: Time-Cap Labs, Inc Farmingdale, NY 11735



Diphenhydramine HCl 25 mg Antihistamine

100 CAPLETS

Sneezing
- Itchy Throat
- Itchy, Watery Eyes

Varnish/Print Omit Area

Runny Nose

Varnish Omit

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredient (in each caplet)

Purnose

Diphenhydramine HCl 25 mg. . . Antihistamine

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)

Varnish Omit

When using this product

- marked drowsiness m avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- excitability may occur, especially in
- 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 1 to 2 caplets years of age and over
- children 6 to under 12 1 caplet years of age
- 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

Allergy Relief Intihistam ine

100 CAPLETS Diphenhydramine HCI 25 Runny Mose - Itchy Throat Sneezing - Itchy, Watery Eyes

NDC 49483-061-01



Allergy Relief

Antihistamine Diphenhydramine HCI 25 mg

Runny Nose

- Sneezing
- Itchy Throat
- · Itchy, Watery Eyes



TAMPER EVIDENT: DO NOT USETHIS 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**

Uses temporarily relieves these symptoms due to hay fever or other upper Active ingredient (in each caplet)
Diphenhydramine HCl 25 mg......

■runny nose ■ itchy, watery eyes ■sneezing ■ itchy nose or throat rtemporarily reliewes these symptoms due to the common cold: respiratory allergies:

runny nose sneezing Warnings

Do not use ■ to make a child sleepy ■ with any other product containing

trouble urinating due to an enlarged prostate gland diphenhydramine, even one used on skin Ask a doctor before use if you have glaucoma

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increase

be careful when driving a motor vehicle or operating machinery

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a Poison Control Center right avray.

Directions at take every 4 to 6 hours
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children 6 to under 12 years of age; I caplet the children 6 to under 12 years of age; I caplet the children 6 to under 12 years.

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

6 years of age

between

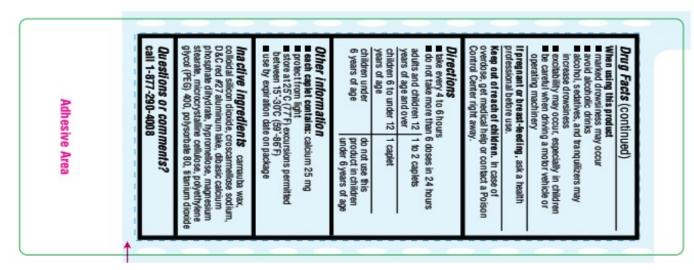
160R 1220

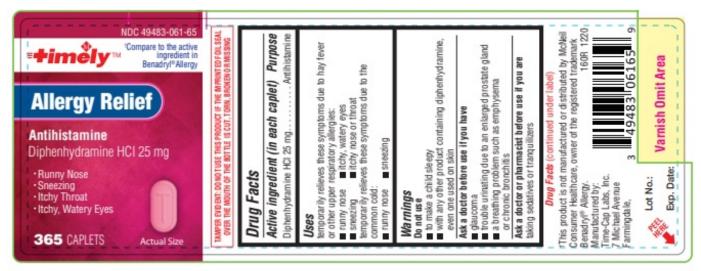
■ protect from light ■ store at 25°C (77°F) excursions permitted 15°-30°C (59°-36°F) ■ use by expiration date on package Questions or comments? call 1-877-290-4008 anufactured by: Time-Cap Labs, Inc. Michael Avenue, Farmingdale, NY 11735 Manufactured by:

LOT EXP.

Varnish Omit Area

DATE





ALLERGY RELIEF

diphenhydramine hydrochloride tablet, film coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:49483-061

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40)
(DIPHENHYDRAMINE - UNII:8GTS82S83M)

DIPHENHYDRAMINE HYDROCHLORIDE

25 mg

Inactive Ingredients			
Ingredient Name	Strength		
CARNAUBA WAX (UNII: R12CBM0EIZ)			
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)			
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			

D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)

DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)

MAGNESIUM STEARATE (UNII: 70097M6I30)

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)

POLYSORBATE 80 (UNII: 6OZP39ZG8H)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

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

P	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