

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

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 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 accidental 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 lke, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol(PEG)400, polysorbate80, titanium dioxide.

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

Adhesive Area

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.

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Directions

- take every 4 to 6 hours
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adults and children 12 years of age and over	1 to 2 caplets
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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

NDC 49483-061-65

timely™

Allergy Relief

Diphenhydramine HCl 25 mg
Antihistamine

For the temporary relief of:

- Runny Nose
- Sneezing
- Itchy Throat
- Itchy, Watery Eyes

365 CAPLETS Actual Size

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 sleep
- with any other product containing diphenhydramine, even one with an unopened container

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

Drug Facts (continued under label)

This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Benadryl Allergy Ultratab®.

Manufactured by:
Time-Cap Labs, Inc.
17 Michael Avenue
Farmingdale, NY 11735
160R 0621

Lot No.: 494831061659
Exp. Date:

PEEL HERE

NDC 49483-061-42

timely™

Allergy Relief

Antihistamine
Diphenhydramine HCl 25 mg

- Runny Nose
- Sneezing
- Itchy Throat
- Itchy, Watery Eyes

24 CAPLETS Actual Size

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

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 sleep
- 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

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

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 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

- 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

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

Manufactured by: Time-Cap Labs, Inc.
160R 1220
17 Michael Avenue, Farmingdale, NY 11735

Lot No.:
Exp. Date:

Varnish Omit Area

Varnish Omit Area

Coating/Print Omit Area



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

Coating Omit

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredient **Purpose**
(in each caplet) 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 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 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
■ each caplet contains: calcium 25 mg
■ protect from light

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 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

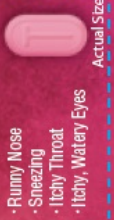
Questions or comments?
call 1-877-290-4008

This 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.
7 Michael Avenue
Farmingdale, NY 11735

NDC 49483-061-42
Compare to the active ingredient in Benadryl® Allergy



Allergy Relief
Antihistamine
Diphenhydramine HCl 25 mg
24 CAPLETS



E826R1 Coating/Print Omit Area

Coating Omit

timely
Allergy Relief
Antihistamine
Diphenhydramine HCl 25 mg
Runny Nose • Itchy Throat
Sneezing • Itchy, Watery Eyes
24 CAPLETS



NDC 49483-061-62

¹Compare to the active ingredient in Benadryl Allergy Ultratab®

Allergy Relief

Diphenhydramine HCl 25 mg Antihistamine

For the temporary relief of:

- Runny Nose
- Sneezing
- Itchy Throat
- Itchy, Watery Eyes

650 CAPLETS



Actual Size

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) 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
- avoid grapefruit juice
- avoid operating machinery or driving a motor vehicle if you feel drowsy or dizzy
- avoid alcohol and grapefruit juice while taking this product
- avoid driving a motor vehicle or operating machinery if you feel drowsy or dizzy
- avoid alcohol and grapefruit juice while taking this product

Drug Facts (continued under label)

This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Benadryl Allergy Ultratab®.

Manufactured by:
Time-Cap Labs, Inc.
7 Michael Avenue
Farmingdale, NY 11735
1160R 0921



3 1160R 0921 8

Lot No.:
Exp. Date:



Varnish Omit Area

Drug Facts (continued)

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

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center (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

- each caplet contains: calcium 25 mg
- protect from light
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
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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

Adhesive Area

Drug Facts (continued)

- 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

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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

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

STOP PEELING

Adhesive Area

Exp. Date: **Varnish Omit Area**
Lot no.:

- marked drowsiness may occur
- When using this product ■ avoid alcoholic drinks
- Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers
- Ask a doctor before use if you have ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- even one used on skin
- Do not use ■ with any other product containing diphenhydramine ■ make a child sleepy

Warnings

- cold: ■ runny nose ■ sneezing
- temporarily relieves these symptoms due to the common ■ sneezing ■ itchy nose or throat
- fever or other upper respiratory allergies
- temporarily relieves these symptoms due to hay

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

Active ingredient (in each caplet) Purpose
Diphenhydramine HCl 25 mg Antihistamine

Drug Facts

3 49483-061-017
N
Farmingdale, NY 11735
Time-Cap Labs, Inc.
7 Maple Avenue
Manufactured by
Heathcote, owner of the registered trademark, Brand™ Allergy 1689 C910

NDC 49483-061-01
ime-Cap Labs, Inc.
Aller-G-Time
Complete Allergy Medicine
Diphenhydramine HCl 25 mg
ANTIHISTAMINE
Compare to the active ingredient of Benadryl®
For the Temporary Relief of:
• Runny Nose
• Sneezing
• Itchy, Watery Eyes
100 CAPLETS
25 mg, EACH



Easy to Swallow

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	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (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			

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 final	part341	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)

Revised: 2/2023

TIME CAP LABORATORIES, INC