DIPHENHYDRAMINE- diphenhydramine hydrochloride capsule
Safetec of America, 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.

Drug Facts

Active ingredient (in each capsule)

Diphenhydramine HCl 25 mg

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itching of the 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

- a breathing problem such as emphysema or chronic bronchitis
- 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
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

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, or as directed by a doctor
- do not take more than 6 times in 24 hours

adults and children 12 years and over	1 to 2 capsules
children 6 to under 12 years	1 capsule
children under 6 years	do not use

Other information

- **each capsule contains:** calcium 20 mg
- store at room temperature 20°-25°C (68°-77°F). Avoid high humidity. Protect from light

Inactive ingredients

benzyl alcohol, butyl paraben, D&C red #28, edible black ink, FD&C blue #1, FD&C red #40, gelatin, lactose, magnesium stearate, methyl paraben, polysorbate 80, propyl paraben, sodium lauryl sulfate

Questions or comments?

Call toll free: **1-800-456-7077**

Principal Display Panel - 25 mg Pouch Label

Safetec
of America, Inc.

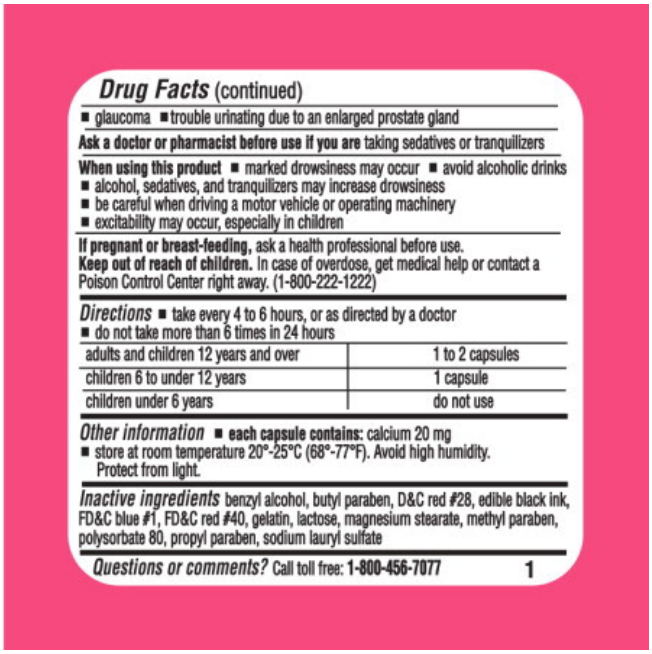
DO NOT USE IF POUCH IS TORN OR DAMAGED

Manufactured for Safetec of America, Inc.
Buffalo NY 14215

Allergy Relief

Diphenhydramine HCl

antihistamine 2 Capsules



Principal Display Panel – 50 Pouches Carton Label

Safetec®
of America, Inc.

*Compare to the active ingredient in Benadryl®

NDC 61010-4409-1

Allergy Relief

Diphenhydramine HCl 25 mg

PUSH TO OPEN

Dispense through opening

Antihistamine

- Itchy Watery Eyes
- Sneezing
- Runny Nose

TAMPER EVIDENT UNIT DOSE POUCHES

DO NOT USE IF POUCH IS TORN OR DAMAGED

50 Pouches 2 Capsules per pouch

Graphic-Untitled

Principal Display Panel – 100 Pouches Carton Label

Safetec®
of America, Inc.

*Compare to the active ingredient in Benadryl®

NDC 61010-4409-2

Allergy Relief

Diphenhydramine HCl 25 mg – Antihistamine

- Itchy Watery Eyes
- Sneezing
- Runny Nose

PUSH TO OPEN

Dispense through opening

TAMPER EVIDENT UNIT DOSE POUCHES

DO NOT USE IF POUCH IS TORN OR DAMAGED

100 Pouches 2 Capsules per pouch

Safetec of America, Inc.

*Compare to the active ingredient in Benadryl®

NDC 61010-4409-2

Allergy Relief

Diphenhydramine HCl 25 mg - Antihistamine

- Itchy Watery Eyes
- Sneezing
- Runny Nose

PUSH TO OPEN
Dispense through opening

TAMPER EVIDENT UNIT DOSE POUCHES
DO NOT USE IF POUCH IS TORN OR DAMAGED

100 Pouches **2** Capsules per pouch

Drug Facts

Active ingredient (in each capsule) — **Purpose**

Diphenhydramine HCl 25 mg ..... Antihistamine

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- temporarily relieves these symptoms due to the common cold: ■ runny nose ■ sneezing

Warnings

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

DO NOT USE IF POUCH IS TORN OR DAMAGED

100 Pouches **2** Capsules per pouch

7 80185 00197 8

Manufactured at an FDA registered facility by
SAFETEC OF AMERICA, INC.
Safetec of America, Inc.
Buffalo NY, 14215
www.safetec.com

FOLD

Safetec of America, Inc.

*Compare to the active ingredient in Benadryl®

Allergy Relief

Diphenhydramine HCl 25 mg - Antihistamine

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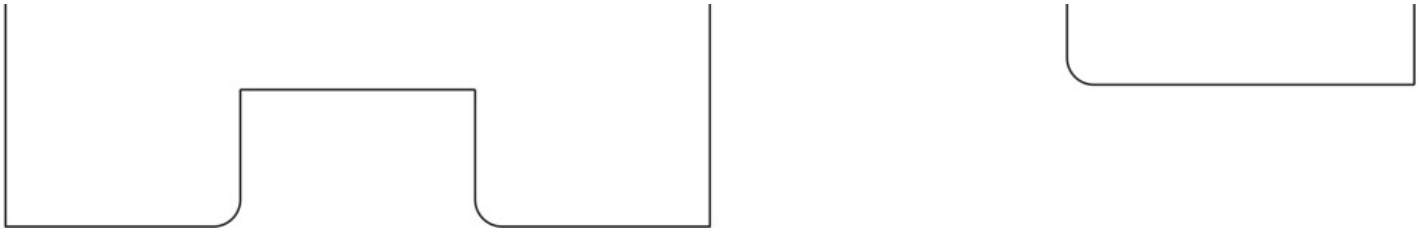

DIPHENHYDRAMINE

diphenhydramine hydrochloride capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61010-4409
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**
benzyl alcohol (UNII: LKG8494WBH)	
butylparaben (UNII: 3QPI1U3FV8)	
D&C red NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics			
Color	pink (PINK) , white (WHITE)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	14mm
Flavor		**Imprint Code**	AP;20
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61010-4409-0	2 in 1 POUCH; Type 0: Not a Combination Product	12/30/2019	

2	NDC:61010-4409-1	50 in 1 BOX	12/30/2019	
2	NDC:61010-4409-0	2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:61010-4409-2	100 in 1 BOX	12/30/2019	
3	NDC:61010-4409-0	2 in 1 POUCH; 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	12/30/2019	

Labeler - Safetec of America, Inc. (874965262)

Revised: 1/2020 Safetec of America, Inc.