ALLERGY RELIEF- diphenhydramine hydrochloride tablet Safrel Pharmaceuticals, 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.

DIPHENHYDRAMINE HCI Tablets, USP 25mg

Active Ingredient

(in each tablet)

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
- itchy nose or throat
- temporarily relieves these symptoms of the common cold:
- runny nose
- sneezing

Warnings

Do not use

- with any other product containing diphenhydramine, even one used on skin
- to make a child sleepy

Ask a doctor before use if you have

- trouble urinating due to an enlarged prostate gland
- glaucoma? a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if youare taking sedatives or tranquilizers

When using this product

- marked drowsiness may occur
- avoid alcoholic drinks
- excitability may occur, especially in children? alcohol, sedatives and tranquilizers may increase drowsiness

• 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, contact a doctor or Poison Control Center immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Do not exceed recommended dosage.

Directions

- take every 4 to 6 hours, not more than 6 doses in 24 hours
- Adults and children 12 years of age and older: 1 or 2 tablets
- children 6 to under 12 years of age: 1 tablet
- children 4 to under 6 years of age: do not use unless directed by a doctor
- children under 4 years of age: do not use

Other Information

- each tablet contains : calcium 20 mg
- store at controlled room temperature 20°-25°C (68°-77°F).
- read all product information before using.
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Inactive Ingredients

Colloidal silicon Dioxide, Croscarmellose Sodium, Dicalcium Phosphate, D & C Red, Magnesium stearate, Microcrystalline cellulose, Polyvinyl alcohol, Titanium dioxide, Talc

Questions or Comments

1-844-384-3723 (Mon-Fri 9AM-5PM EST) or www.safrelpharma.com

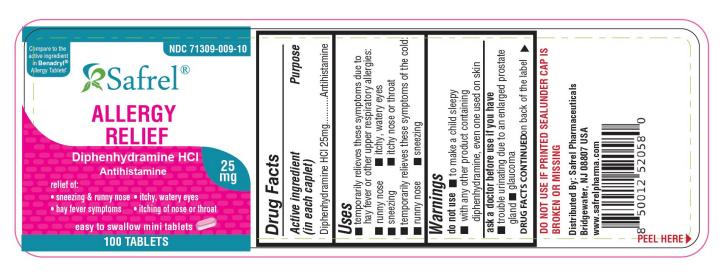
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL DIPHENHYDRAMINE HYDROCHLORIDE TABLET

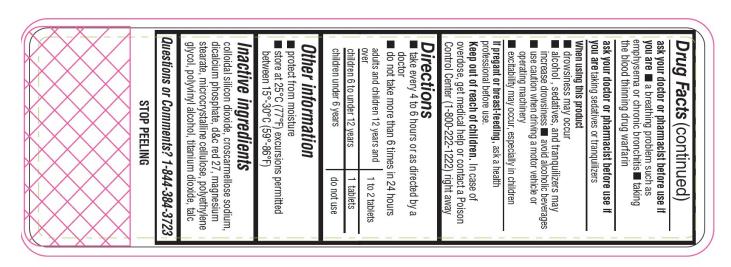
, USP 25 MG

ANTIHISTAMINE

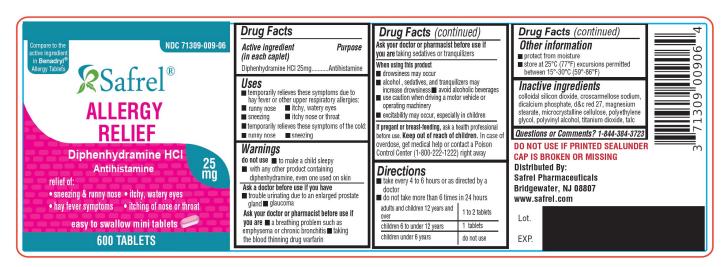
* This product is not manufactured or distributed by McNeil-Consumer Healthcare, owner of the registered trademark Benadryl Allergy.

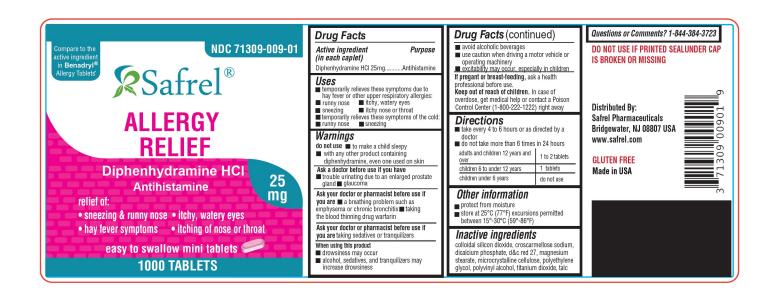
71309-109-10 100 Caplets





71309-109-06 600 Caplets





ALLERGY RELIEF

diphenhydramine hydrochloride tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71309-009

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	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)		
D&C RED NO. 27 (UNII: 2LRS185U6K)		
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
POLYVINYL ALCOHOL (UNII: 532B59J990)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

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

Contains **Packaging Marketing Start Marketing End Item Code Package Description Date Date** NDC:71309-009-1 in 1 CARTON 01/01/2016 30 30 in 1 BOTTLE; Type 0: Not a Combination 1 **Product** NDC:71309-009- 100 in 1 BOTTLE; Type 0: Not a Combination 2 05/12/2012 Product NDC:71309-009- 1000 in 1 BOTTLE; Type 0: Not a Combination 05/12/2012 01 Product NDC:71309-009- 600 in 1 BOTTLE; Type 0: Not a Combination 05/12/2012 06 **Product** NDC 71309-009-30 "COMPARE TO Benedry! Allergy ACTIVE INGREDIENT Purpose Antihistamine ask your doctor or pharmacist before use if you are Distributed by: Safre! Pharmaceuticals LLC, Bidgewater, NJ 08807 www.safrelpharma.com gland ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis SEE CARTON FOR COMPLETE DRUG FACTS alcohol, sedatives and tranquilizers may increase take every 4 to 6 hours, or as directed by a excitability may occur, especially in children Adults and children 12 years and over: 1 or 2 do not take more than 6 doses in 24 hours be careful when driving a motor vehicle or children 6 to under 12 years of age: 1 caplet children under 6 years of age: do not use with any other product containing diphenhydramine, even one used on skin ask a doctor before use if you have trouble unnating due to an enlarged DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING taking sedative or tranquilizers. marked drowsiness may occur avoid alcoholic drinks iphenhydramine HCI 25mg Active ingredient When using this product to make a child sleepy in each caplet) Drug Facts operating machinery Allergy relief for: - Sneezing - Itchy, watery eyes - Running nose - Itchy throat Warnings Directions rowsiness do not use Exp. Date: 30 Tablets

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part341	05/12/2012			

Labeler - Safrel Pharmaceuticals, LLC. (080566287)

Revised: 2/2022 Safrel Pharmaceuticals, LLC.