

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 HCl 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 you are 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

Compare to the active ingredient in Benadryl® Allergy Tablets

NDC 71309-009-10

Safrel®

ALLERGY RELIEF

Diphenhydramine HCl
Antihistamine

25 mg

relief of:

- sneezing & runny nose
- itchy, watery eyes
- hay fever symptoms
- itching of nose or throat


easy to swallow mini tablets

100 TABLETS

Drug Facts	<p>Active ingredient (in each caplet) Diphenhydramine HCl 25mg.....Antihistamine</p> <p>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 of the cold: ■ runny nose ■ sneezing</p>
Warnings	<p>do not use ■ to make a child sleepy</p> <p>■ with any other product containing diphenhydramine, even one used on skin</p> <p>ask a doctor before use if you have</p> <p>■ trouble urinating due to an enlarged prostate gland ■ glaucoma</p> <p>DRUG FACTS CONTINUED on back of the label</p>

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

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Bridgewater, NJ 08807 USA
www.safrelpharma.com



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PEEL HERE →

STOP PEELING

Drug Facts (continued)	<p>ask your doctor or pharmacist before use if you are ■ a breathing problem such as emphysema or chronic bronchitis ■ taking the blood thinning drug warfarin</p> <p>ask your doctor or pharmacist before use if you are taking sedatives or tranquilizers</p> <p>When using this product</p> <p>■ drowsiness may occur</p> <p>■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ avoid alcoholic beverages</p> <p>■ use caution when driving a motor vehicle or operating machinery</p> <p>■ excitability may occur, especially in children</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away</p>				
Directions	<p>take every 4 to 6 hours or as directed by a doctor</p> <p>■ do not take more than 6 times in 24 hours</p> <p>adults and children 12 years and over</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>children 6 to under 12 years</td> <td>1 to 2 tablets</td> </tr> <tr> <td>children under 6 years</td> <td>do not use</td> </tr> </table>	children 6 to under 12 years	1 to 2 tablets	children under 6 years	do not use
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children under 6 years	do not use				
Other information	<p>■ protect from moisture</p> <p>■ store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)</p>				
Inactive ingredients	<p>colloidal silicon dioxide, croscarmellose sodium, dicalcium phosphate, d&c red 27, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, titanium dioxide, talc</p>				

Questions or Comments? 1-844-384-3723

71309-109-06 600 Caplets

Compare to the active ingredient in Benadryl® Allergy Tablets

NDC 71309-009-06

Safrel®

ALLERGY RELIEF

Diphenhydramine HCl
Antihistamine

25 mg


relief of:

- sneezing & runny nose
- itchy, watery eyes
- hay fever symptoms
- itching of nose or throat

easy to swallow mini tablets

600 TABLETS


Drug Facts	<p>Active ingredient (in each caplet) Diphenhydramine HCl 25mg.....Antihistamine</p> <p>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 of the cold: ■ runny nose ■ sneezing</p> <p>Warnings do not use ■ to make a child sleepy ■ with any other product containing diphenhydramine, even one used on skin</p> <p>ask a doctor before use if you have</p> <p>■ trouble urinating due to an enlarged prostate gland ■ glaucoma</p> <p>ask your doctor or pharmacist before use if you are ■ a breathing problem such as emphysema or chronic bronchitis ■ taking the blood thinning drug warfarin</p>						
Drug Facts (continued)	<p>ask your doctor or pharmacist before use if you are taking sedatives or tranquilizers</p> <p>When using this product</p> <p>■ drowsiness may occur</p> <p>■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ avoid alcoholic beverages</p> <p>■ use caution when driving a motor vehicle or operating machinery</p> <p>■ excitability may occur, especially in children</p> <p>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 (1-800-222-1222) right away</p> <p>Directions</p> <p>take every 4 to 6 hours or as directed by a doctor</p> <p>■ do not take more than 6 times in 24 hours</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>adults and children 12 years and over</td> <td>1 to 2 tablets</td> </tr> <tr> <td>children 6 to under 12 years</td> <td>1 tablet</td> </tr> <tr> <td>children under 6 years</td> <td>do not use</td> </tr> </table>	adults and children 12 years and over	1 to 2 tablets	children 6 to under 12 years	1 tablet	children under 6 years	do not use
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Drug Facts (continued)	<p>Other information</p> <p>■ protect from moisture</p> <p>■ store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)</p> <p>Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, dicalcium phosphate, d&c red 27, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, titanium dioxide, talc</p> <p>Questions or Comments? 1-844-384-3723</p> <p>DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING</p> <p>Distributed By: Safrel Pharmaceuticals Bridgewater, NJ 08807 www.safrel.com</p> <p>Lot. [REDACTED]</p> <p>EXP. [REDACTED]</p>						



3 71309 00906 4

71309-109-01 1000 Caplets

Compare to the active ingredient in **Benadryl®** Allergy Tablets



ALLERGY RELIEF

Diphenhydramine HCl
Antihistamine

25 mg

relief of:

- sneezing & runny nose
- itchy, watery eyes
- hay fever symptoms
- itching of nose or throat

easy to swallow mini tablets

1000 TABLETS

Drug Facts

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

Diphenhydramine HCl 25mg.....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 of the 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

- trouble urinating due to an enlarged prostate gland
- glaucoma

Ask your doctor or pharmacist before use if you are

- a breathing problem such as emphysema or chronic bronchitis
- taking the blood thinning drug warfarin

Ask your doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product

- drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness

Drug Facts (continued)

- avoid alcoholic beverages
- use caution 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 (1-800-222-1222) right away

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 tablets
children 6 to under 12 years	1 tablet
children under 6 years	do not use

Other information

- protect from moisture
- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients


colloidal silicon dioxide, croscarmellose sodium, dicalcium phosphate, d&c red 27, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, titanium dioxide, talc

Questions or Comments? 1-844-384-3723

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

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Bridgewater, NJ 08807 USA
www.safrel.com

GLUTEN FREE
Made in USA



3 71309 00901 9

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

Contains

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-009-30	1 in 1 CARTON	01/01/2016	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:71309-009-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/12/2012	
3	NDC:71309-009-01	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/12/2012	
4	NDC:71309-009-06	600 in 1 BOTTLE; Type 0: Not a Combination Product	05/12/2012	



SEE CARTON FOR COMPLETE DRUG FACTS
Drug Facts

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

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 your doctor or pharmacist before use if you are
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- DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

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Lot No.:
Exp. Date:

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.