ALLERGY RELIEF DIPHENHYDRAMINE HCL 25 MG ANTIHISTAMINEdiphenhydramine hcl bar, chewable Strategic Sourcing Services 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.

Allergy Relief Diphenhydramine HCI 25 mg ANTIHISTAMINE

DRUG FACTS

Active ingredient (in each piece)

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
- itching of the nose or throat
- temporarily relieves these symptoms due to the common cold:
- runny nose
- sneezing

Warnings

Do not use

- To make 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 (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 hour

Age (yr)	Dose (Piece)
Adults and children 12 year	ars and over1 to 2 Pieces (25 mg to 50 mg)
Children 6 to 11 years	1 Piece (25 mg)
Children under 6 years	Do not use

Other information

• each piece: contains sodium 9 mg.

Low sodium

- store in a cool dry place between 20-25°C (68-77°F).
- Child Resistant Container; do not use if printed seal under cap is broken or missing.

Inactive ingredients:

FD&C Red# 40, flavors, geleol mono and diglycerides, glucose syrup, gum arabic, hydroxypropyl betadex, maltitol solution, neotame, polyethylene glycol 400, povidone K30, propylene glycol, purified water, seaweed extract (carrageenan), sodium chloride, starch, sucralose, sucrose, trisodium citrate dihydrate.

Questions or comments?

Call **833-358-6431**

Monday to Friday 9:00am to 7:00pm EST

Principal display Panel-25 mg Bottle label

NDC 70677-1059-1 COMPARE TO THE ACTIVE INGREDIENT IN BENADRYL $^{\circledR}$ ALLERGY *

Foster & Thrive TM

ALLERGY RELIEF

Diphenhydramine HCI

25 mg

Antihistamine

Mixed Berry Flavor

Gummy Bite

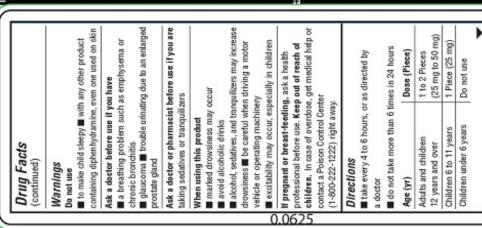
For relief of:

- Sneezing
- Runny nose
- Itchy, Watery eyes & Itchy Throat

ACTUAL SIZE

20 PIECES





Inactive ingredients: FD&C Red #40, flavors geleol mono and diglycerides, glucose syrup, gum carrageeran), sodium chloride, starch, sucralose nectame, polyethylene glycol 400, povidone K30, propylene glycol, purified water, seaweed extract arabic, hydroxypropyl betadex, maltitol solution, Child Resistant Container; do not use if printed seal under cap is broken or missing Call 833-358-6431 Monday to Friday 9:00am to 7:00pm EST each piece contains sodium 9 mg. store in a cool dry place between sucrose, trisodium citrate dihydrate. Questions or comments? Other information 20-25°C (68-77°F). Low sodium

ALLERGY RELIEF DIPHENHYDRAMINE HCL 25 MG ANTIHISTAMINE

diphenhydramine hcl bar, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-1059
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		
FD&C RED NO. 40 (UNII: WZB9127XOA)			
CORN SYRUP (UNII: 9G5L16BK6N)			
ACACIA (UNII: 5C5403N260)			
HYDROXYPROPYL BETADEX (UNII: 11960HX6EK)			
GLYCERYL MONO AND DIPALMITOSTEARATE (UNII: KC98RO82HJ)			
MALTITOL (UNII: D65DG142WK)			
NEOTAME (UNII: VJ597D52EX)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
POVIDONE K30 (UNII: U725QWY32X)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
CARRAGEENAN (UNII: 5C69YCD2YJ)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
STARCH, CORN (UNII: 08232NY3SJ)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
SUCROSE (UNII: C151H8M554)			
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)			

Product Characteristics			
Color	pink (Light pink to red pink)	Score	no score
Shape	RECTANGLE	Size	23mm
Flavor	BERRY (Mixed Berry)	Imprint Code	
Contains			

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:70677- 1059-1	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2023	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/27/2023	

Labeler - Strategic Sourcing Services LLC (116956644)

Establishment

Name	Address	ID/FEI	Business Operations
USpharma Ltd		080664601	manufacture(70677-1059)

Revised: 4/2023

Strategic Sourcing Services LLC