

**ALLERGY RELIEF DIPHENHYDRAMINE HCl 25 MG ANTIHISTAMINE-
diphenhydramine 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 HCl 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 years and over	1 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:

citric acid, FD&C red #40, flavor, glucose syrup, hydroxypropyl betadex, magnesium stearate, maltitol solution, maltodextrin, neotame, 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 carton label

sunmark

COMPARE TO BENADRYL® ALLERGY active ingredient

NDC 70677-1062-1

Soft Chews

allergy relief Diphenhydramine HCl, 25 mg | Antihistamine

Allergy Relief for:

Sneezing

Runny Nose

Itchy, Watery Eyes

Itchy Throat

Bubble Gum Flavor

Chewy Bites

Actual Size 10 PIECES



ALLERGY RELIEF DIPHENHYDRAMINE HCl 25 MG ANTIHISTAMINE

diphenhydramine hcl bar, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-0162
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CORN SYRUP (UNII: 9G5L16BK6N)	
HYDROXYPROPYL BETADEX (UNII: 1I96OHX6EK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTITOL (UNII: D65DG142WK)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
NEOTAME (UNII: VJ597D52EX)	
WATER (UNII: 059QF0KO0R)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
STARCH, CORN (UNII: O8232NY3SJ)	
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	BUBBLE GUM	Imprint Code	o
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-0162-1	1 in 1 CARTON	06/22/2022	
1		10 in 1 BOTTLE, PLASTIC; 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	06/22/2022	

Labeler - Strategic Sourcing Services LLC (116956644)

Establishment

Name	Address	ID/FEI	Business Operations
USpharma Ltd		080664601	manufacture(70677-0162)