FIRSTCARE ALLERGY RELIEF DIPHENHYDRAMINE HCl, 25 MG ANTIHISTAMINE-
diphenhydramine hcl bar, chewable
USpharma Ltd

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.

FIRSTCARE 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:

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 1-800-227-6151

USpharma

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13900 NW 57th Court, Miami Lakes, FL 33014

1-800-227-6151 www.uspharmaltd.com

Principal display Panel-25 mg Bottle label

FIRSTCARE NDC 71594-708-08

*****MADE IN USA*** Patent Pending**

ALLERGY RELIEF Diphenhydramine HCl 25 mg Antihistamine

Gummy Bite Mixed Berry Flavor

Relief of:

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

20 PIECES

FIRSTCARE ALLERGY RELIEF DIPHENHYDRAMINE HCL, 25 MG ANTIHISTAMINE

diphenhydramine hcl bar, chewable

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71594-708
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: 5C5403N26O)	
HYDROXYPROPYL BETADEX (UNII: 1I96OHX6EK)	
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: 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	BERRY (Mixed Berry)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71594-708-08	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/03/2023	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph final	part341	04/14/2023	

Labeler - USpharma Ltd (080664601)

Establishment

Name	Address	ID/FEI	Business Operations
USpharma Ltd		080664601	manufacture(71594-708)

Revised: 5/2023 USpharma Ltd