

**DIPHENHYDRAMINE HCL 12.5MG ANTIHISTAMINE- diphenhydramine hydrochloride bar, chewable**  
**Alexso, Inc**

*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.*

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**Diphenhydramine HCl Soft Chew**

**Diphenhydramine HCl 12.5 mg Soft Chews**

**Alexso, Inc.**

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**Diphenhydramine HCl 12.5 mg Soft Chews**

***DRUG FACTS***

**ACTIVE INGREDIENT (in each soft chew)**

Diphenhydramine HCl 12.5mg

**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

**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**

- Excitability may occur, especially in children
- Marked drowsiness may occur
- Avoid alcoholic drinks
- 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 overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

## **DIRECTIONS**

### **Adults and children 12 years and over:**

- Take 2 to 4 soft chews (25 mg to 50 mg) every 4 to 6 hours, or as directed by a doctor
- Do not take more than 6 times in 24 hours
- Chew each soft chew thoroughly before swallowing

### **Children 6 to 11 years:**

- Take 1 to 2 soft chews (12.5 mg to 25 mg) every 4 to 6 hours, or as directed by a doctor.
- Do not take more than 6 times in 24 hours
- Chew each soft chew thoroughly before swallowing

**Children under 6 years:** Do not use

## **OTHER INFORMATION**

- each soft chew contains: **sodium 7 mg**. Very 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, flavor, glucose syrup, hydroxypropyl betadex, magnesium stearate, maltitol solution, maltodextrin, mineral oil, neotame, purified water, seaweed extract (carrageenan), sodium chloride, starch, sucralose, sucrose, trisodium citrate dihydrate.

## **Questions or comments?**

Call 888-495-6078

## **HOW SUPPLIED**

Diphenhydramine 12.5mg Soft Chews is supplied in the following dosage form:

Twenty (20) Soft Chews per container

\*\*\*Made in USA\*\*\*

Manufactured for:  
Alexso, Inc.  
2317 Cotner Ave  
Los Angeles, CA 90064

NDC: 50488-4125-1  
Size: 20 Soft Chews

## **PRINCIPAL DISPLAY PANEL**

Diphenhydramine HCl 12.5 mg Soft Chews  
20 Bubble Gum Flavored Gummies

Chewy Gummy Bites  
NDC: 50488-4125-1 Patent Pending

**Diphenhydramine HCl**  
12.5mg Antihistamine

*ADD SUGAR*  
*FLAVORED*

CHWY BITES

Antihistamine  
• Runny Nose & Sneezing  
• Itchy Throat or Nose  
• Itchy, Watery Eyes

20 SOFT CHEWS

NDC: 50488-4125-1 Patent Pending

**Drug Facts**

**Active ingredient** (in each soft chew)  
Diphenhydramine Hydrochloride  
HCl 12.5 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

**Warnings**  
Do not use  
• To make child sleepy with any other product containing diphenhydramine, even one used on skin

Continued Under Label 33386749

**Alexso Inc.**  
Manufactured for: Alexso, Inc.  
Los Angeles, CA 90064 | 888-495-6078

NO UV CODING AREA

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MADE IN THE USA

Peel Here

**Drug Facts**  
(continued)

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**Other information**

- each soft chew contains sodium 7 mg, very 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, flavor, glucose syrup, hydroxypropyl betadex, magnesium stearate, methylcellulose solution, polyethylene glycol, polyethylene glycol, purified water, seaweed extract (carrageenan), sodium chloride, starch, sucralose, sucrose, trisodium citrate dihydrate.

**Questions or comments?**  
Call 888-495-6078

## DIPHENHYDRAMINE HCL 12.5MG ANTIHISTAMINE

diphenhydramine hydrochloride bar, chewable

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50488-4125
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg

### Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ANHYDROUS DEXTROSE (UNII: 5SLOG7R0OK)	
HYDROXYPROPYL BETADEX (UNII: 1I96OHX6EK)	

<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)
<b>MALTITOL</b> (UNII: D65DG142WK)
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)
<b>NEOTAME</b> (UNII: VJ597D52EX)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)
<b>CORN SYRUP</b> (UNII: 9G5L16BK6N)
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)
<b>SUCROSE</b> (UNII: C151H8M554)
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)

### Product Characteristics

<b>Color</b>	YELLOW (Light yellow to golden brown)	<b>Score</b>	no score
<b>Shape</b>	RECTANGLE	<b>Size</b>	18mm
<b>Flavor</b>	BUBBLE GUM	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50488-4125-1	20 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	02/08/2021	

**Labeler** - Alexso, Inc (963338061)

Revised: 2/2021

Alexso, Inc