

**CALMCO SLEEP AID GUMMY BITE- diphenhydramine hcl bar, chewable**  
**CalmCo LLC**

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**CalmCo Adult Sleep Aid Gummy Bite**

**Active Ingredient (in each piece)**

Diphenhydramine HCl 25 mg

**Purpose**

Nighttime Sleep Aid

**Uses**

- For the relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

**Do not use**

- for children under 12 years of age
- 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**

avoid alcoholic drinks

**Stop use and ask a doctor if**

sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness

**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 only 1 dose per day (24 hours)
- Chew each piece thoroughly before swallowing

## Dosage Chart

### Age (Years)

Adults and children 12 years and over  
children under 12 years

### Dose (Piece)

1 to 2 pieces (25 mg to 50 mg)  
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 of Comments?

Call 941-203-4590 or visit [www.calmco.com](http://www.calmco.com)



# Sleep Aid

## Gummy Bites

Diphenhydramine HCl, 25 mg / piece

**20 Pieces**

For Adult Use Only

Fall asleep faster  
Sleep soundly  
Non-habit forming

Free from:  
Allergens  
Alcohol  
Parabens

**Drug Facts**

**Active ingredient (in each piece)** Purpose  
Diphenhydramine HCl 25 mg Nighttime Sleep Aid

**Uses**  
■ For the relief of occasional sleeplessness  
■ reduces time to fall asleep if you have difficulty falling asleep

**Warnings**  
**Do not use:** ■ for children under 12 years of age  
■ 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** avoid alcoholic drinks

**Stop use and ask a doctor if** sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness

**Drug Facts continued on reverse side**

Made in the USA:  
Distributed by CalmCo LLC  
Sarasota FL 34240

CCSA-L-001-01  
51111225



3 13992 00097 113

No UV Coating here  
25.4mm x 18mm

Peel here

**Drug Facts** (Continued)

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**Questions or comments?**

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STOP PEELING

**calmco**

## CALMCO SLEEP AID GUMMY BITE

diphenhydramine hcl bar, chewable

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73282-2518
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>MALTITOL</b> (UNII: D65DG142WK)	
<b>GLYCERYL MONO AND DIPALMITOSTEARATE</b> (UNII: KC98RO82HJ)	
<b>NEOTAME</b> (UNII: VJ597D52EX)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B6978945GQ)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>CORN SYRUP</b> (UNII: 9G5L16BK6N)	
<b>HYDROXYPROPYL BETADEX</b> (UNII: 1I96OHX6EK)	
<b>ACACIA</b> (UNII: 5C5403N26O)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	score with uneven pieces
<b>Shape</b>	RECTANGLE	<b>Size</b>	15mm
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73282-2518-1	25 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/12/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	12/12/2023	

**Labeler** - CalmCo LLC (079308308)

**Registrant** - CalmCo LLC (079308308)

Revised: 12/2023

CalmCo LLC