

**SAMBROSA NIGHT- doxylamine succinate syrup**  
**Sambrosa Care, Inc.**

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***Active Ingredients***

Each 3 mL dose contains Doxylamine succinate 9.78 mg

***Purpose***

Doxylamine succinate 9.78 mg.....Antihistamine

***Uses***

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- sneezing
- runny nose
- itchy, watery eyes
- itching of the nose or throat

***Warnings***

**Ask a doctor before use if you have**

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- difficulty 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 beverages
- 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 right away

***Directions***

- take only as directed
- use provided measurement spoon, look at calibration marks. A full spoon equals 5 mL.

- adults and children 12 years of age and over: oral dosage is 7.5 to 12.5 milligrams every 4 to 6 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor
- children 6 to under 12 years of age: oral dosage is 3.75 to 6.25 milligrams every 4 to 6 hours, not to exceed 37.5 milligrams in 24 hours, or as directed by a doctor
- children under 6 years of age: consult a physician

### ***Other Information***

store in a refrigerator after opening at 35-41 degrees F (2-5 degrees C)

### ***Inactive Ingredients***

Citric Acid, Glycerin, Herbal alcohol-water extract blend from 7 organic herbs (California Poppy, Hawthorn, Hops, Mistletoe, Oat, Passion flower, White chestnut) Honey, Potassium Sorbate, Sugar, Tragacanth, Vanilla, and Water.

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Night Syrup

For allergy relief to have a good night's rest

With Doxylamine (antihistamine) 9.78 mg

In a great-tasting base of honey and 7 organic herbs.

300mL

10.14 fl oz

Alcohol 3% vol.



**Tamper evident:** Do not use if the bottom ring of the cap is broken away from the upper part of the cap. Failure to follow these warnings could result in serious consequences.

### Drug Facts

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Each 3 mL dose contains:  
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#### Warnings

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Keep carton for important Drug Facts information

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**Inactive ingredients** Citric acid, glycerin, herbal alcohol-water extract blend from 7 organic herbs (California poppy, Hawthorn, Hops, Mistletoe, Oat, Passion flower, White chestnut), honey, potassium sorbate, sugar, tragacanth, vanilla and water.

#### Questions or comments?

Call 1-800-651-6952  
Mon-Fri between 9 am and 5 pm PST

Distributed by Sambrosa Care USA  
9171 Wilshire Boulevard, Suite 500  
Beverly Hills, CA 90210  
www.sambrosa.com  
Made in the Netherlands

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### Night Syrup

For allergy relief to have a good night's rest

With Doxylamine (antihistamine) 9.78 mg  
In a great-tasting base of honey and 7 organic herbs.



300mL  
10.14 fl oz

Alcohol 3% vol.

### Relief. Rest. Restore.

Sambrosa approaches sleep differently. With non-habit forming Doxylamine and a proprietary base of honey and seven organic herbs, Sambrosa provides allergy relief so you can have a good night's rest.

- Crafted in the Netherlands, with Dutch sourced ingredients
- Nutrient-rich honey
- Antihistamine Doxylamine
- No dyes, no synthetic colors or flavors
- No high fructose corn syrup

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### Questions or comments?

Call 1-800-651-6652  
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## Night Syrup

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With Doxylamine (antihistamine) 9.78 mg  
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100mL  
3.38 fl oz

Alcohol 3% vol.

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## SAMBROSA NIGHT

doxylamine succinate syrup

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60665-003
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	9.78 mg in 3 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>CRATAEGUS LAEVIGATA FRUIT</b> (UNII: D5RZ7MF1YF)	
<b>OAT</b> (UNII: Z6J799EAKJ)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PASSIFLORA INCARNATA FLOWERING TOP</b> (UNII: CLF5YFS110)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>AESCULUS HIPPOCASTANUM SEED OIL</b> (UNII: E0M52HIR1Y)	
<b>HONEY</b> (UNII: Y9H1V576FH)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>TRAGACANTH</b> (UNII: 2944357O2O)	
<b>VANILLA</b> (UNII: Q74T35078H)	
<b>VISCUM ALBUM FRUITING TOP</b> (UNII: BK9092J5MP)	
<b>ESCHSCHOLZIA CALIFORNICA</b> (UNII: 9315HN272X)	
<b>HOPS</b> (UNII: 01G73H6H83)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60665-003-01	1 in 1 CARTON	01/10/2020	
1		100 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:60665-003-03	1 in 1 CARTON	01/10/2020	
2		300 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:60665-003-02	1 in 1 CARTON	12/01/2020	
3		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:60665-003-04	3 mL in 1 POUCH; Type 0: Not a Combination Product	10/26/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/10/2020	

**Labeler** - Sambrosa Care, Inc. (079116527)

## Establishment

Name	Address	ID/FEI	Business Operations
Lelypharma bv		408688237	manufacture(60665-003)

