

SAMBROSA NIGHT- doxylamine succinate syrup
Lelypharma bv

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
- use caution 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 doctor.

Inactive Ingredients

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

Other Information

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

sambrosa

sweet dreams

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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Keep carton for important Drug Facts information

Drug Facts (continued)

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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

sambrosa
sweet dreams



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

sweet dreams



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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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80148-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients				
Ingredient Name				Strength
OAT (UNII: Z6J799EAJK)				
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
SUCROSE (UNII: C151H8M554)				
TRAGACANTH (UNII: 2944357O2O)				
ESCHSCHOLZIA CALIFORNICA (UNII: 9315HN272X)				
AESCULUS HIPPOCASTANUM SEED OIL (UNII: E0M52HIR1Y)				
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				
VANILLA (UNII: Q74T35078H)				
CRATAEGUS LAEVIGATA FRUIT (UNII: D5RZ7MF1YF)				
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS11O)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
HONEY (UNII: Y9H1V576FH)				
VISCUM ALBUM FRUITING TOP (UNII: BK9092J5MP)				
HOPS (UNII: 01G73H6H83)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80148-001-01	1 in 1 CARTON	01/10/2020	
1		100 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:80148-001-03	1 in 1 CARTON	01/10/2020	
2		300 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:80148-001-02	1 in 1 CARTON	12/01/2020	
3		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:80148-001-04	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 - Lelypharma bv (408688237)

Establishment

Name	Address	ID/FEI	Business Operations
Lelypharma bv		408688237	manufacture(80148-001)

