

**SORE THROAT- echinacea purpurea, plantago major, baptisia tinctoria, phytolacca decandra, apis mellifica, belladonna, lachesis mutus, mercurius solubilis, hepar sulphuris calcareum spray
Nova Aurora Corp**

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

DRUG FACTS:

ACTIVE INGREDIENTS:

Echinacea Purpurea 2X, Plantago Major 2X, Baptisia Tinctoria 3X, Phytolacca Decandra 3X, Apis Mellifica 12X, Belladonna 12X, Lachesis Mutus 12X, Mercurius Solubilis 12X, Hepar Sulphuris Calcareum 15X.

INDICATIONS:

For the temporary symptomatic relief of minor pain associated with sore throat, difficulty swallowing, speaking, hoarseness or canker sores.

WARNINGS:

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.

Do not use if tamper evident seal is broken or missing.

Store in a cool, dry place.

WARNING: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a physician promptly. Do not use more than two days or administer to children under 3 years of age unless directed by a physician.

Recommended for Professional Use.

KEEP OUT OF REACH OF CHILDREN:

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

Adults and children over 12 years of age, at the onset of symptoms, spray throat every 3 hours. Consult a physician for use in children under 12 years of age.

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INACTIVE INGREDIENTS:

Demineralized Water, 23% Ethanol, Glycerin, Herbal Base [Clove (Flower), Goldenseal (Root), Myrrh

(Resin), Sage (Leaf), Thyme (Leaf)], Marshmallow Flavor, Menthol, Spearmint Oil (flowering tops), Stevia (leaf) Extract, Teaberry Oil Flavor.

QUESTIONS:

Manufactured Exclusively For:

NSI and Nova Aurora Corp

P.O. Box 97227

Pittsburgh, PA 15209

www.phpltd.com

PACKAGE LABEL DISPLAY:

PROFESSIONAL HEALTH PRODUCTS

SORE THROAT

SPRAY

HOMEOPATHIC

C63 (reorder code)

NET 1 FL. OZ. (30 ML)

Recommended for Professional Use.

WARNINGS: 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. Do not use if tamper evident seal around bottle is broken or missing. Store in a cool, dry place.

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Lot# XXXXX

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53173-0001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ECHINACEA PURPUREA (UNII: QI7G114Y98) (ECHINACEA PURPUREA - UNII:QI7G114Y98)	ECHINACEA PURPUREA	2 [hp_X] in 1 mL
PLANTAGO MAJOR (UNII: W2469WNO6U) (PLANTAGO MAJOR - UNII:W2469WNO6U)	PLANTAGO MAJOR	2 [hp_X] in 1 mL
BAPTISIA TINCTORIA ROOT (UNII: 5EF0HWI5WU) (BAPTISIA TINCTORIA ROOT - UNII:5EF0HWI5WU)	BAPTISIA TINCTORIA ROOT	3 [hp_X] in 1 mL
PHYTOLACCA AMERICANA ROOT (UNII: 11E6VI8VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6VI8VEG)	PHYTOLACCA AMERICANA ROOT	3 [hp_X] in 1 mL
APIS MELLIFERA (UNII: 7S82P3R43Z) (APIS MELLIFERA - UNII:7S82P3R43Z)	APIS MELLIFERA	12 [hp_X] in 1 mL
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	12 [hp_X] in 1 mL
LACHESIS MUTA VENOM (UNII: VSW71SS07I) (LACHESIS MUTA VENOM - UNII:VSW71SS07I)	LACHESIS MUTA VENOM	12 [hp_X] in 1 mL
MERCURIUS SOLUBILIS (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)	MERCURIUS SOLUBILIS	12 [hp_X] in 1 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	15 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CLOVE (UNII: K48IKT5321)	
GOLDENSEAL (UNII: ZW3Z11D0JV)	
MYRRH (UNII: JC71GJ1F3L)	
SAGE (UNII: 065C5D077J)	
THYME (UNII: CW6570BU4N)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
MENTHOL (UNII: L7T10EP3A)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
SPEARMINT OIL (UNII: C3M81465G5)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MARSHMALLOW	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53173-0001-1	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/09/2015	

Labeler - Nova Aurora Corp (032439395)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(53173-0001) , api manufacture(53173-0001) , label(53173-0001) , pack(53173-0001)

Revised: 10/2015

Nova Aurora Corp