# SAMBUCUS COLD FLU RELIEF ELDERBERRY- sambucus cold flu relief elderberry syrup Schwabe North America

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.

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## Sambucus Cold + Flu Relief Elderberry Syrup

### **Active Ingredients**

Pelargonium sidoides 1x

Aconitum napellus 4x

Eucalyptus globulus 2x

Sambucus nigra 3x

Bryonia 4x

Eupatorium perfoliatum 6x

Gelsemium sempervirens 4x

Phosphorus 6x

Ipecacuanha 3x

## **Inactive Ingredients**

Citric Acid

Elderberry Extract

Ethyl Alcohol

Glycerin

Lactose Monohydrate

Maltodextrin

**Natural Flavor** 

Potassium Sorbate

Purified Water

Sorbitol

## **Indications & Usage**

Temporarily relieves flu symptoms. Shortens duration and reduces severity of symptoms associated with the common cold and throat/nasal/bronchial irritations:

chills/fever, chest congestion, cough, headache, hoarseness, body aches, sore throat, sneezing/runny nose, nasal congestion.

## **Dosage & Administration**

Directions:

For best results, use at first sign of symptoms and continue to use for an additional 48 hours after symptoms cease.

Shake well before each use.

Use only with enclosed dosage cup.

Adults & children 13 years of age and older: take  $1\frac{1}{2}$  teaspoons (tsp) (7.5 mL) three times daily.

Children 6 to 12 years of age: take 1 teaspoon (tsp) (5mL) three times daily.

Children under 6 years of age: consult a doctor.

### **Purpose**

Temporarily relieves flu symptoms. Shortens duration and reduces severity of symptoms associated with the common cold and throat/nasal/bronchial irritations: chills/fever, chest congestion, cough, headache, hoarseness, body aches, sore throat, sneezing/runny nose, nasal congestion.

## **Warnings**

Sore throat warning: if sore throat is severe, persists more than 2 days, is accompanied or followed by a fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

#### Ask Doctor

Ask a doctor before use if you have: a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema, a cough that is accompanied by excessive phlegm (mucus), been taking any medications, an allergy to plants of the Geraniaceae family.

## Stop Use

Stop use and ask a doctor if new symptoms occur, symptoms get worse or last more than 7 days, fever worsens or lasts more than 3 days, cough lasts more then 7 days or occurs with rash or persistent headache.

These could be signs of a serious condition.

## **Pregnancy or Breastfeeding**

If pregnant or breast-feeding, ask a healthcare professional before use.

### Keep out of reach of children

Keep out of reach of children.

#### Overdose

In case of overdose, seek medical help or contact a Poison Control Center right away.



# SAMBUCUS COLD FLU RELIEF ELDERBERRY

sambucus cold flu relief elderberry syrup

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53499-1513
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
<b>PELARGONIUM SIDOIDES ROOT</b> (UNII: H6J53HEX8E) (PELARGONIUM SIDOIDES ROOT - UNII: H6J53HEX8E)	PELARGONIUM SIDOIDES ROOT	1 [hp_X] in 120 mL		
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	4 [hp_X] in 120 mL		
<b>EUCALYPTUS GLOBULUS LEAF</b> (UNII: \$546YLW6E6) (EUCALYPTUS GLOBULUS LEAF - UNII: \$546YLW6E6)	EUCALYPTUS GLOBULUS LEAF	2 [hp_X] in 120 mL		
<b>SAMBUCUS NIGRA FLOWERING TOP</b> (UNII: CT03BSA18U) (SAMBUCUS NIGRA FLOWERING TOP - UNII:CT03BSA18U)	SAMBUCUS NIGRA FLOWERING TOP	3 [hp_X] in 120 mL		
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	4 [hp_X] in 120 mL		
<b>EUPATORIUM PERFOLIATUM FLOWERING TOP</b> (UNII: 1W0775VX6E) (EUPATORIUM PERFOLIATUM FLOWERING TOP - UNII:1W0775VX6E)	EUPATORIUM PERFOLIATUM FLOWERING TOP	6 [hp_X] in 120 mL		
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	4 [hp_X] in 120 mL		
IPECAC (UNII: 62I3C8233L) (IPECAC - UNII:62I3C8233L)	IPECAC	3 [hp_X] in 120 mL		
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	6 [hp_X] in 120 mL		

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
EUROPEAN ELDERBERRY (UNII: BQY1UBX046)			
ALCOHOL (UNII: 3K9958V90M)			
GLYCERIN (UNII: PDC6A3C0OX)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)			

Product Characteristics		
Color		Score
Shape		Size
Flavor	BERRY (RASPBERRY AND ELDERBERRY FLAVOR)	Imprint Code
Contains		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:53499- 1513-4	1 in 1 BOX	11/20/2024		
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
	11/20/2024		
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date	

# Labeler - Schwabe North America (831153908)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Schwabe North America, Inc.		831153908	manufacture(53499-1513)	

Revised: 11/2024 Schwabe North America