

**COLD RELIEF ALCOHOL FREE CHERRY SYRUP- pelargonium sidoides syrup
Schwabe North America, Inc**

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.

Cold Relief Alcohol Free Cherry Syrup

Active Ingredient

PELARGONIUM SIDOIDES 1X

Inactive Ingredients

ARONIA JUICE

CITRIC ACID

ETHYL ALCOHOL

FRUCTOSE

GLYCERIN

MALTODEXTRIN

NATURAL FLAVOR

POTASSIUM SORBATE

PURIFIED WATER

Dosage & Administration:

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 and children 13 years of age and older: Take 1 1/2 teaspoon (tsp) (7.5mL) three times daily.

Children 6-12 years of age: Take 1 teaspoon (5mL) three times daily.

Children under 1-5 years of age: Take 1/2 teaspoon (2.5 mL) three times daily.

Indications and Usage Section

Shortens duration and reduces severity of symptoms associated with the common colds and throat/sinus/bronchial irritations: congestion, cough, hoarseness, sore throat.

Purpose

Shortens duration and reduces severity of symptoms associated with the common colds and throat/sinus/bronchial irritations: congestion, cough, hoarseness, sore throat.

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.

Individuals with allergies to plants of the Geraniaceae family should use this product with caution.

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 than 7 days or occurs with rash or persistent headache.
These could be signs of a serious condition.

Pregnancy or Breast Feeding

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.



Add image transcription here...

COLD RELIEF ALCOHOL FREE CHERRY SYRUP

pelargonium sidoides syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53499-4463
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PELARGONIUM SIDOIDES ROOT (UNII: H6J53HEX8E) (PELARGONIUM SIDOIDES ROOT - UNII:H6J53HEX8E)	PELARGONIUM SIDOIDES ROOT	1 [hp_X] in 120 mL

Inactive Ingredients

Ingredient Name	Strength
ARONIA MELANOCARPA FRUIT JUICE (UNII: D2EVP827PJ)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ALCOHOL (UNII: 3K9958V90M)	
FRUCTOSE (UNII: 6YSS42VSEV)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
WATER (UNII: 059QF0KO0R)	
POTASSIUM SORBATE (UNII: 1VPU26JZ Z 4)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	Score
Shape	Size
Flavor	Imprint Code
CHERRY (NATURAL CHERRY FLAVOR)	
Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499-4463-4	3 in 1 CARTON	05/22/2023	
1		120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		05/22/2023	

Labeler - Schwabe North America, Inc (831153908)

Establishment

Name	Address	ID/FEI	Business Operations
Schwabe North America, Inc		831153908	manufacture(53499-4463)

Establishment

Name	Address	ID/FEI	Business Operations
ProSolutions, Inc.		070769782	label(53499-4463) , pack(53499-4463)

Revised: 5/2023

Schwabe North America, Inc