COLD RELIEF ZERO SUGAR GRAPE- 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 Zero Sugar Grape Syrup

Active Ingredient

Pelargonium sidoides 1X

Inactive Ingredients

Citric Acid

Ethyl Alcohol

Glycerin

Maltodextrin

Natural Flavor

Potassium Sorbate

Purified Water

Red Cabbage Juice Color

Sorbitol

Dosage and 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 $\frac{1}{2}$ teaspoon (tsp) (7.5 mL) three times daily.

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

Children under 6 years of age: Consult a doctor.

Indications & Usage

Shortens duration and reduces severity of symptoms associated with the common cold and throat/nasal/bronchial irritations: chest congestion, nasal congestion, cough,

hoarseness, sore throat.

Purpose

Shortens duration and reduces severity of symptoms associated with the common cold and throat/nasal/bronchial irritations: chest congestion, nasal 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 the 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.

Stope 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, or 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, seeek medical help or contact a Poison Control Center immediatley.



Add image transcription here...

COLD RELIEF ZERO SUGAR GRAPE

pelargonium sidoides syrup				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53499-6794	
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			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
ALCOHOL (UNII: 3K9958V90M)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
WATER (UNII: 059QF0KO0R)				
CABBAGE (UNII: GW0W1Y9I97)				
SORBITOL (UNII: 506T60A25R)				
GLYCERIN (UNII: PDC6A3C0OX)				
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE (NATURAL GRAPE FLAVOR)	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499- 6794-5	1 in 1 CARTON	03/06/2024	
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		03/06/2024	
		03/06/2024	

Labeler - Schwabe North America, Inc (831153908)

Establishment				
Name	Address	ID/FEI	Business Operations	
Schwabe North America		831153908	manufacture(53499-6794)	

Revised: 3/2024 Schwabe North America, Inc