

COLD RELIEF DROPS- pelargonium sidoides liquid
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 Drops

Active Ingredient

Pelargonium sidoides 1x

Inactive Ingredient

Citric Acid

Ethyl Alcohol

Glycerin

Maltodextrin

Potassium Sorbate

Purified Water

Sorbitol

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.

Adults & children 13 years of age and older: Take 1.5 mL three times daily by mouth.

Children 6-12 years of age: Take 1 mL three times daily by mouth.

Children 1-5 years of age: Take 0.5 mL three times daily by mouth.

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 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 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.

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Overdose

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



Add image transcription here...

COLD RELIEF DROPS

pelargonium sidoides liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53499-8271
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 30 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499-8271-8	1 in 1 CARTON	08/26/2024	
1		59 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:53499-8271-4	1 in 1 CARTON	08/26/2024	
2		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		08/26/2024	

Labeler - Schwabe North America, Inc. (831153908)

Establishment

Name	Address	ID/FEI	Business Operations
Schwabe North America, Inc.		831153908	manufacture(53499-8271)

Revised: 8/2024

Schwabe North America, Inc.