

COLD RELIEF KIDS FASTACTIVES CHERRY- pelargonium sidoides powder
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 Kids Cherry FastActives

Active Ingredient

Pelargonium sidoides 1X

Inactive Ingredients

Citric Acid

Malic Acid

Maltodextrin

Natural Flavor

Silica

Xylitol

Dosage & Administration

Tear packet open, pour contents into mouth and swallow.

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

Adults and children 13 years of age and older: take contents of 1 packet three times daily

Children 6-12 years of age: take contents of 1 packet two 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.

Warning

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 plant in 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.

Pregnant or breast feeding

If you are 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 KIDS FASTACTIVES CHERRY

pelargonium sidoides powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53499-2166
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 700 mg

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MALIC ACID (UNII: 817L1N4CKP)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

XYLITOL (UNII: VCQ006KQ1E)

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499-2166-0	10 in 1 CARTON	07/18/2024	
1		700 mg in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/18/2024	

Labeler - Schwabe North America, Inc. (831153908)

Registrant - Schwabe North America, Inc. (831153908)

Establishment

Name	Address	ID/FEI	Business Operations
Schwabe North America, Inc.		831153908	manufacture(53499-2166)

Establishment

Name	Address	ID/FEI	Business Operations
ProSolutions, Inc.		070769782	label(53499-2166) , pack(53499-2166)

Revised: 7/2024

Schwabe North America, Inc.