

UMCKA COLDCARE LEMON- pelargonium sidoides powder

ProSolutions, 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.

Active Ingredient

Drug Facts	
<i>Active ingredient (in each packet)</i>	<i>Purpose</i>
Pelargonium sidoides 1X	Shortens duration and reduces severity of upper respiratory symptoms

Inactive Ingredients

Inactive ingredients citric acid, maltodextrin, natural flavor, silica, turmeric color, xylitol
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Dosage and Administration

Directions	
■ Dissolve contents of 1 packet in 4-6 ounces of hot water and sip while hot. May also be dissolved in 4-6 ounces of cold water, which may be preferable for children.	
■ For best results, use at the first sign of symptoms and continue to use for an additional 48 hours after symptoms cease.	
Age	Dose
Adults & children 13 years of age and older	Take 3 times daily.
Children 6-12 years of age	Take 2 times daily.
Children under 6 years of age	Consult a doctor.

Indications and Usage

Uses
■ Shortens duration and reduces severity of symptoms associated with the common cold and throat/nasal/bronchial irritations:
■ congestion ■ cough ■ hoarseness ■ sore throat

Warnings

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 a Doctor

Ask a doctor before use if you

- have persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- have a cough that is accompanied by excessive phlegm (mucus)
- are taking any medications
- have 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. In case of overdose, seek medical help or contact a Poison Control Center immediately.

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Over dosage

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Purpose

Uses

■ Shortens duration and reduces severity of symptoms associated with the common cold and throat/nasal/bronchial irritations:

- congestion
- cough
- hoarseness
- sore throat

Package Panel



UMCKA COLDCARE LEMON

pelargonium sidoides powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83102-5146
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 5 g

Inactive Ingredients

Ingredient Name	Strength
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
TURMERIC (UNII: 856YO1Z64F)	
XYLITOL (UNII: VCQ006KQ1E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	LEMON (Natural Lemon Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83102-5146-0	10 in 1 CARTON	02/24/2023	
1		5 g 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		02/24/2023	

Labeler - ProSolutions, Inc. (070769782)

Establishment

Name	Address	ID/FEI	Business Operations
ProSolutions, Inc.		070769782	label(83102-5146) , pack(83102-5146)

Establishment

Name	Address	ID/FEI	Business Operations
Schwabe North America, Inc.		831153908	manufacture(83102-5146)