

UMCKA MENTHOL- 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.

Umcka Mint-Menthol Syrup

Active Ingredient

PELARGONIUM SIDOIDES 1X

Inactive Ingredient

ETHYL ALCOHOL

FRUCTOSE

GLYCERIN

MALTODEXTRIN

MENTHOL

NATURAL FLAVOR

PURIFIED WATER

Dosage & Administration

Directions

For best results, use at first sign of symptoms.

Continue to use for an additional 48 hours after symptoms cease.

Use only with enclosed dosage cup.

Adults & children 12 years of age and older: Take 1 1/2 teaspoon (tsp) (7.5 mL) 3 times daily.

Children under 12 years of age: Consult a physician.

Indications & Usage

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

Purpose

Shortens duration and reduces severity of symptoms associated with common colds

and throat/nasal/bronchial irritations: congestion, cough, hoarseness, sore throat.

Warnings

Sore throat warning: severe or persistent sore throat for more than 2 days or if accompanied by a high fever, headache, nausea, vomiting, or rash may be serious.

Consult a physician promptly.

Ask Doctor

Ask a doctor before use if you have a persistent or chronic cough that lasts, is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or is accompanied by excessive phlegm (mucus).

Stop Use

Stop use and ask the doctor if new symptoms occur, symptoms worsen or do not get better within 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

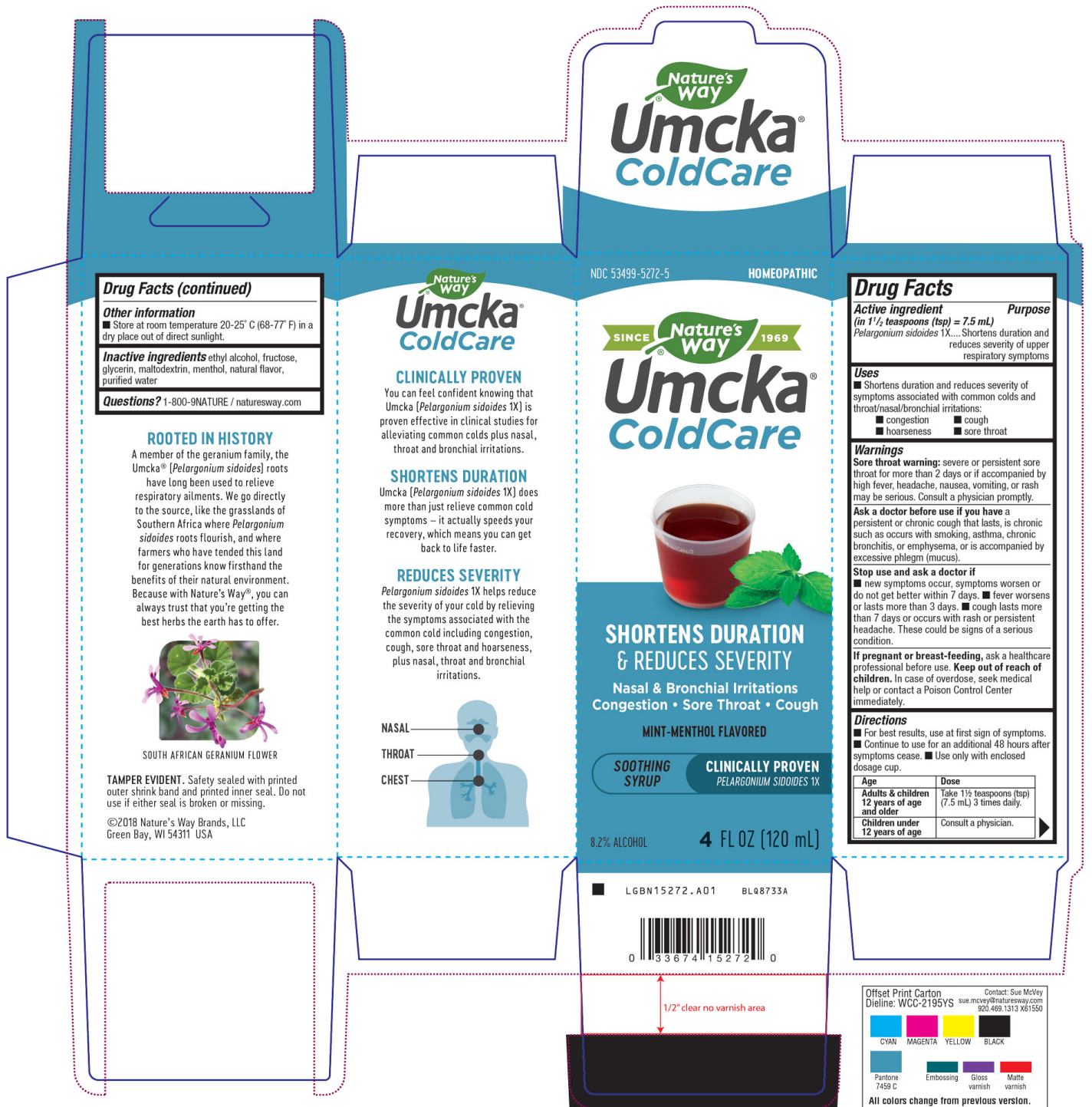
If pregnant or breast-feeding, ask a healthcare professional before use.

Keep out of reach of children.

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Overdose

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



Add image transcription here...

UMCKA MENTHOL			
pelargonium sidoides syrup			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53499-5272
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
ALCOHOL (UNII: 3K9958V90M)	
FRUCTOSE (UNII: 6YSS42VSEV)	
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MENTHOL (NATURAL MENTHOL FLAVOR) , SPEARMINT (NATURAL SPEARMINT FLAVOR)		Imprint Code
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499-5272-5	1 in 1 CARTON	01/01/2006	
1		120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:53499-5272-9	1 in 1 CARTON	01/01/2006	
2		240 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		01/01/2006	

Labeler - Schwabe North America, Inc (831153908)**Establishment**

Name	Address	ID/FEI	Business Operations
Schwabe North America, Inc		831153908	manufacture(53499-5272)

