

## **UMCKA COLDCARE STARTER KIT- umcka coldcare starter kit**

### **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.*

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## **Umcka ColdCare Starter Kit**

### **Active Ingredient**

Umcka CC Cherry Syrup: Pelargonium sidoides 1X

Soothing Hot Drink-Lemon Packet: Pelargonium sidoides 1X

### **Inactive Ingredients**

Umcka CC Cherry Syrup: aronia juice, citric acid, ethyl alcohol, fructose, glycerin, maltodextrin, natural flavors, potassium sorbate, purified water

Soothing Hot Drink-Lemon Packet: citric acid, maltodextrin, natural flavor, silica, turmeric (color), xylitol

### **Indications & Usage**

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

Soothing Hot Drink-Lemon Packet: Shortens duration and reduces severity of symptoms associated with common colds and throat/nasal/bronchial irritations: congestion, cough, headache, hoarseness, sore throat.

### **Purpose**

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

Soothing Hot Drink-Lemon Packet: Shortens duration and reduces severity of symptoms associated with common colds and throat/nasal/bronchial irritations: congestion, cough, headache, hoarseness, sore throat.

### **Warnings**

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

Consult a physician promptly.

Soothing Hot Drink-Lemon Packet: Sore Throat Warning: severe or persistent sore throat for more than 2 days or if accompanied by high fever, headache, nausea, vomiting, or rash may be serious.

Consult a physician promptly.

## **Ask Doctor**

Umcka CC Cherry Syrup: 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).

Soothing Hot Drink-Lemon Packet: 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**

Umcka CC Cherry Syrup: Stop use and ask a doctor if new symptoms occur, symptoms worsen or do not get better within 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.

Soothing Hot Drink-Lemon Packet: Stop use and ask a doctor if new symptoms occur, symptoms worsen or do not get better within 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**

Umcka CC Cherry Syrup: If pregnant or breast-feeding, ask a healthcare professional before use.

Soothing Hot Drink-Lemon Packet: If pregnant or breast-feeding, ask a healthcare professional before use.

## **Keep out of Reach of Children**

Umcka CC Cherry Syrup: Keep out of reach of children.

Soothing Hot Drink-Lemon Packet: Keep out of reach of children.

## **Overdose**

Umcka CC Cherry Syrup: In case of overdose, seek medical help or contact a Poison Control Center immediately.

Soothing Hot Drink-Lemon Packet: In case of overdose, seek medical help or contact a Poison Control Center immediately.

## **DOSAGE & ADMINISTRATION**

### Directions

#### Umcka CC Cherry Syrup:

For best results, use at first sign of symptoms and 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 6 - 11 years of age: Take 1 teaspoon (5 mL) 3 times daily

Children under 6 years of age: Consult a physician

#### Soothing Hot Drink-Lemon Packet:

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.

Adults & children 12 years of age and older: Take 3-4 times daily

Children 6-11 years of age: Take 2-3 times daily

Children under 6 years of age: Consult a physician



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## UMCKA COLD CARE STARTER KIT

umcka coldcare starter kit kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53499-2137
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### Packaging



#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499-2137-1	1 in 1 CARTON	10/09/2017	02/28/2026

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	120 mL
Part 2	1 PACKET	5 g

**Part 1 of 2**

**UMCKA COLD CARE ALCOHOL FREE CHERRY**

pelargonium sidoides syrup

**Product Information**

Item Code (Source)	NDC:53499-5273
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 240 mL

**Inactive Ingredients**

Ingredient Name	Strength
ARONIA MELANOCARPA FRUIT JUICE (UNII: D2EVP827PJ)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ALCOHOL (UNII: 3K9958V90M)	
FRUCTOSE (UNII: 6YSS42VSEV)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	

**Product Characteristics**

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:53499-5273-5	1 in 1 CARTON		
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			

Part 2 of 2

UMCKA COLDCARE LEMON

pelargonium sidoides powder

Product Information

Item Code (Source)	NDC:53499-5146
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TURMERIC (UNII: 856YO1Z64F)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	LEMON	Imprint Code	
Contains			

Packaging



#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499-5146-0	10 in 1 CARTON		
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			

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/09/2017	02/28/2026

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

### Establishment

Name	Address	ID/FEI	Business Operations
Schwabe North America, Inc.		831153908	manufacture(53499-2137)