UMCKA COLDCARE DAY PLUS NIGHT- umcka coldcare day plus night
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 ColdCare Day + Night

Active Ingredient

Umcka CC Day: Pelargonium sidoides 1X

Umcka CC Night: Pelargonium sidoides 1X

Chamomilla recutila 2X

Humulus Lupulus 1X

Passiflora incarnate 1X

Inactive Ingredient

Umcka CC Day: Citric acid, maltodextrin, natural flavor, silica, turmeric color, xylitol.
Umcka CC Night: Citric acid, honey, lactose monohydrate, lou han guo, maltodextrin, natural flavor, silica, stevia leaf extract, turmeric color, xylitol.

Doage & Administration

Directions

Umcka CC Day: 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 1 packet 2 times daily

Children 6-11 years of age: Take 1 packet 2 times daily

Children under 6 years of age: Consult a doctor

Umcka CC Night: 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 1 packet 30 minutes prior to bedtime

Children 6-11 years of age: Take 1/2 packet 30 minutes prior to bedtime

Children under 6 years of age: Consult a doctor

Indications & Usage

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

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

Umcka CC Night: 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 Day: Sore throat warning: severe or presistent 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.

Umcka CC Night: Sore throat warning: severe or presistent 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 Day: Ask a doctor before use if you have a 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 any allergy to plants of the Geraniaceae family.

Umcka CC Night: Ask a doctor before use if you have a 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 any allergy to plants of the Geraniaceae family.

Stop Use

Umcka CC Day: 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.

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

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

Keep out of reach of children.

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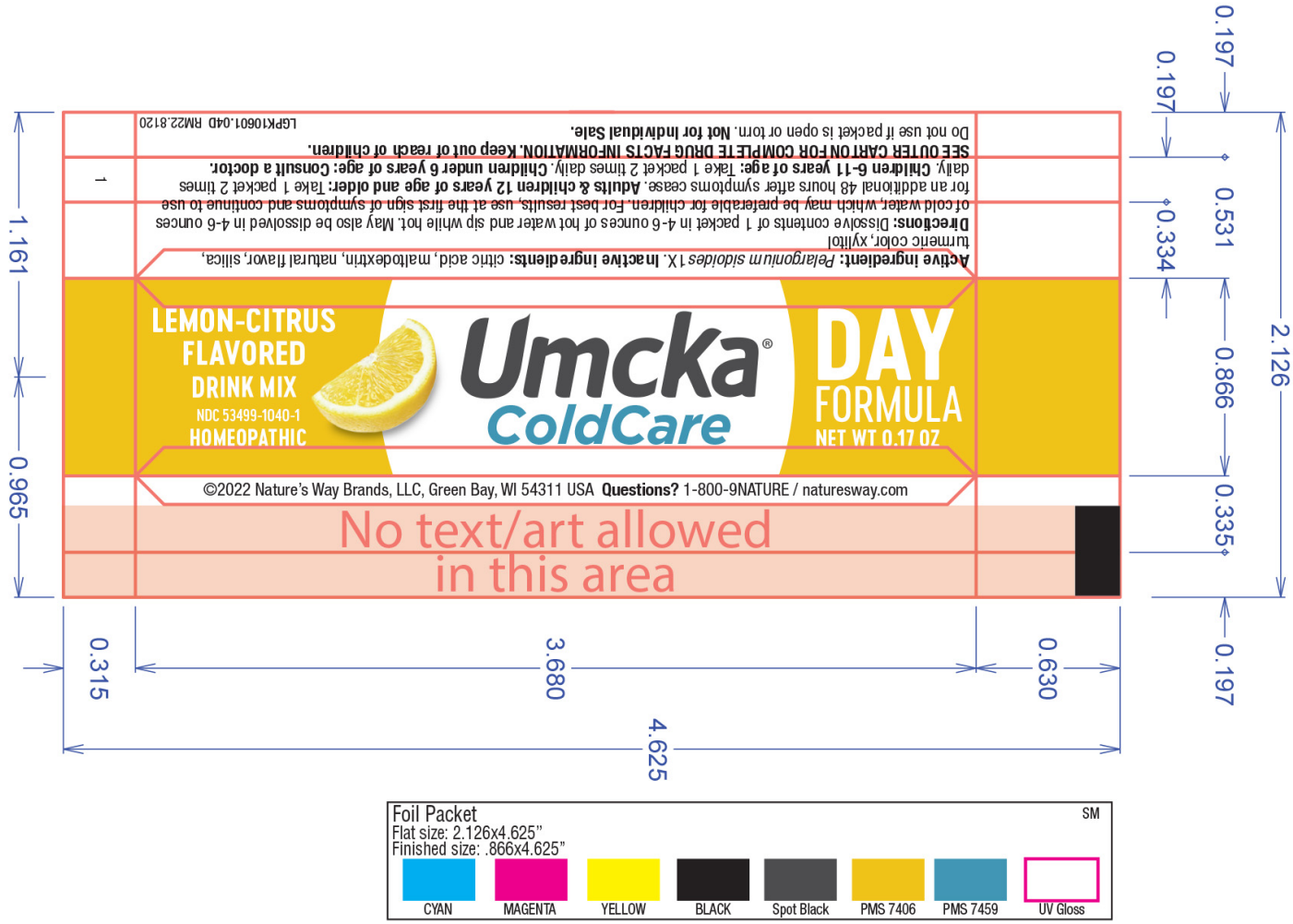
Overdose

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

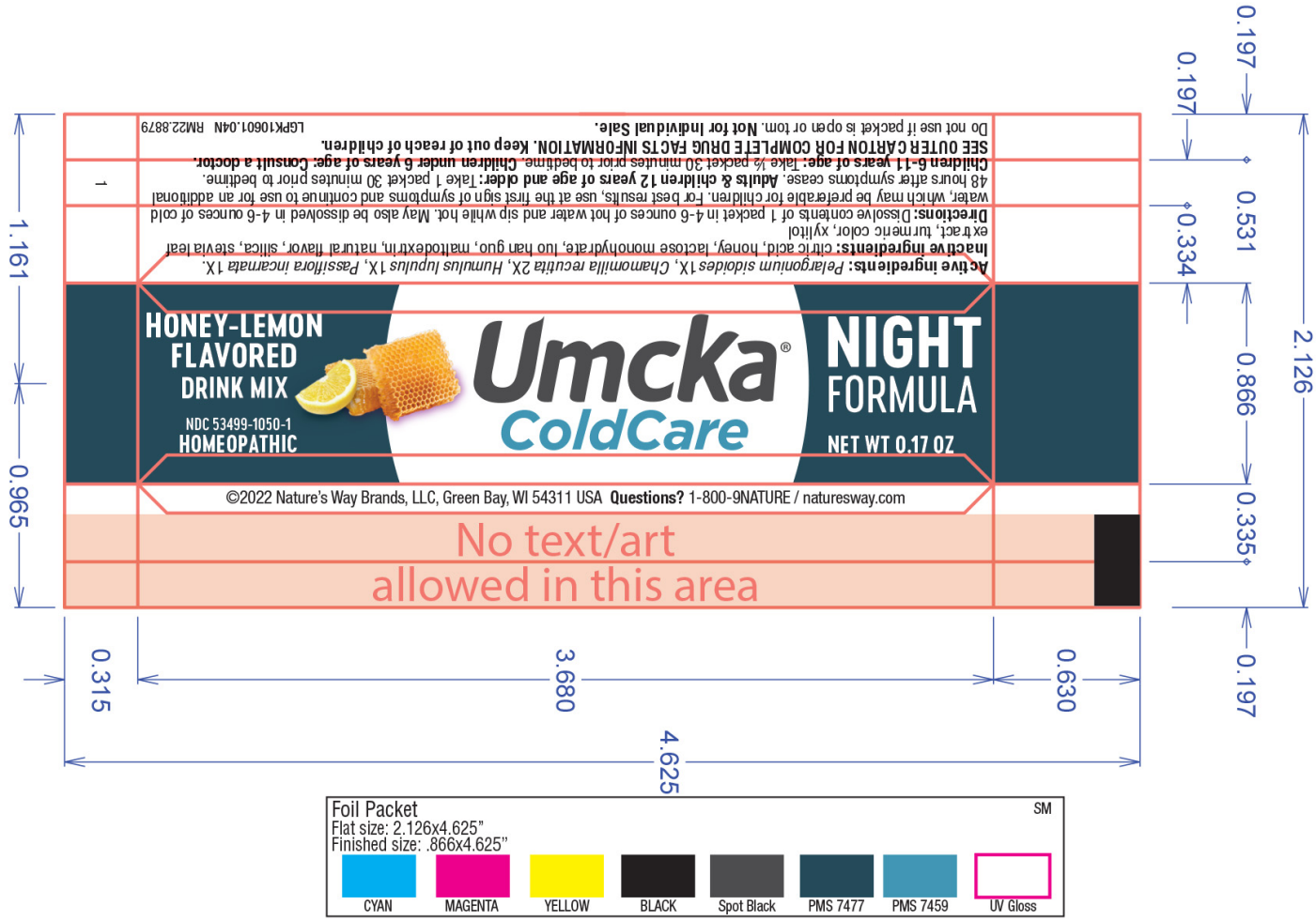
Umcka CC Night: In case of overdose, seek medical help or contact a Poison Control Center immediately.



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UMCKA COLDCARE DAY PLUS NIGHT

umcka coldcare day plus night kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53499-1060

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499-1060-1	1 in 1 CARTON	12/09/2015	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 POUCH	5 g
Part 2	1 POUCH	5 g

Part 1 of 2

UMCKA COLDCARE DAY

pelargonium sidoides root powder

Product Information	
Item Code (Source)	NDC:53499-1040
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**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TURMERIC (UNII: 856YO1Z64F)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	LEMON, CITRUS	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53499-1040-1	8 in 1 PACKAGE		
1		5 g in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/09/2015	

Part 2 of 2

UMCKA COLDCARE NIGHT

pelargonium sidoides root, chamomile, humulus lupulus whole, passiflora incarnata whole powder

Product Information

Item Code (Source)	NDC:53499-1050
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
CHAMOMILE (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)	CHAMOMILE	2 [hp_X] in 5 g
HUMULUS LUPULUS WHOLE (UNII: 912A6Q1N4A) (HUMULUS LUPULUS WHOLE - UNII:912A6Q1N4A)	HUMULUS LUPULUS WHOLE	1 [hp_X] in 5 g
PASSIFLORA INCARNATA WHOLE (UNII: R48E2W2LMO) (PASSIFLORA INCARNATA WHOLE - UNII:R48E2W2LMO)	PASSIFLORA INCARNATA WHOLE	1 [hp_X] in 5 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HONEY (UNII: Y9H1V576FH)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SIRAITIA GROSVENORII FRUIT (UNII: NOU2FB51TW)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEVIA LEAF (UNII: 6TC6NN0876)	
TURMERIC (UNII: 856YO1Z64F)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	HONEY, LEMON	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499-1050-1	4 in 1 PACKAGE		
1		5 g in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/09/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/09/2015	

Labeler - Schwabe North America, Inc. (831153908)

Establishment

Name	Address	ID/FEI	Business Operations
Schwabe North America, Inc.		831153908	manufacture(53499-1060)

Establishment

Name	Address	ID/FEI	Business Operations
ProSolutions, Inc.		070769782	label(53499-1060) , pack(53499-1060)

Revised: 5/2023 Schwabe North America, Inc.