COLD RELIEF DAY PLUS NIGHT- cold relief 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.

Cold Relief Day Plus Night

Active Ingredient

Cold Relief Day:

Pelargonium sidoides 1X

Cold Relief Night:

Pelargonium sidoides 1X

Chamomilla recutita 2X

Humulus lupulus 1X

Passiflora incarnata 1X

Inactive Ingredient

Cold Relief Day: Citric Acid, Maltodextrin, Natural Flavor, Silica, Turmeric Color, Xylitol.

Cold Relief Night: Citric Acid, Honey, Lactose Monohydrate, Lou Han Guo, Maltodextrin, Natural Flavor, Silica, Stevia Leaf Extract, Turmeric Color, Xylitol.

Dosage & Administration

Directions

Cold Relief 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 with Cold Relief Hot Drink Night Formula at the first sign of symptoms and continue to use for an additional 48 hours after symptoms cease.

Adults/Children 13 years of age and older: Take 1 packet two times daily

Children 6-12 years of age: Take 1 packet daily

Children under 6 years of age: Consult a doctor

Cold Relief 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 with Cold Relief Hot Drink Day Formula at the first sign of symptoms and continue to use for an additional 48 hours after symptoms cease.

Adults/Children 13 years of age and older: Take 1 packet nightly 30-60 minutes before

bed

Children 6-12 years of age: Take 1 packet nightly 30-60 minutes before bed

Children under 6 years of age: Consult a doctor

Indications & Usage

Cold Relief Day: 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

Cold Relief Night: 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

Cold Relief Day: 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

Cold Relief Night: 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

Warnings

Cold Relief Day: 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.

Cold Relief Night: 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

Cold Relief Day: 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 plants of the Geraniaceae family.

Cold Relief Night: 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 plants of the Geraniaceae family.

Stop Use

Cold Relief Day: 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.

Cold Relief Night: 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

Cold Relief Day: If pregnant or breast-feeding, ask a healthcare professional before use.

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

Keep out of reach of children.

Cold Relief Day: Keep out of reach of children.

Cold Relief Night: Keep out of reach of children.

Overdose

Cold Relief Day: In case of overdose, seek medical help or contact a Poison Control Center right away.

Cold Relief Night: In case of overdose, seek medical help or contact a Poison Control Center right away.

Add image transcription here...

COLD RELIEF DAY PLUS NIGHT

cold relief day plus night kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53499-2060

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499-2060-1	1 in 1 CARTON	05/22/2024	

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

COLD RELIEF DAY

cold relief day powder

Product Information	
Item Code (Source)	NDC:53499-2040
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:53499-2040-1	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		05/22/2024	

Part 2 of 2

COLD RELIEF NIGHT

cold relief night powder

Product Information

Item Code (Source)	NDC:53499-2050
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:53499-2050-1	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		05/22/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		05/22/2024	

Labeler - Schwabe North America, Inc. (831153908)

Establishment

Name	Address	ID/FEI	Business Operations
Schwabe North America, Inc.		831153908	manufacture(53499-2060)

Establishment

Name	Address	ID/FEI	Business Operations
ProSolutions, Inc.		070769782	label(53499-2060) , pack(53499-2060)

Revised: 5/2024 Schwabe North America, Inc.