

**ALLERGY AND SINUS RELIEF- pelargonium sidoides root, hydrastis canadensis whole, potassium chloride, sanguinaria canadensis root, pulsatilla vulgaris, silicon dioxide tablet, chewable
Schwabe North American, 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.

Allergy and Sinus Relief

Active Ingredient

Pelargonium sidoides 1X

Hydrastis canadensis 6X

Kali muriaticum 3X

Sanguinaria canadensis 6X

Pulsatilla 6X

Silicea 6X

Inactive Ingredient

Citric Acid

Lactose Monohydrate

Magnesium Stearate

Malic Acid

Maltodextrin

Mannitol

Natural Flavor

Sodium Croscarmellose

Sorbitol

Sour Cherry Powder

Stearic acid

Xylitol

Purpose

Temporarily relieves allergy and sinus symptoms.

Shortens duration and reduces severity of symptoms associated with the common cold

and throat, nasal, bronchial irritations: cough, headache, hoarseness, sore throat, sinus pressure, chest congestion, nasal congestion, sneezing/runny nose, shrinks swollen nasal membranes, promotes sinus drainage, burning, itchy eyes, helps decongest sinus openings and passages.

Indications & Usage

Temporarily relieves allergy and sinus symptoms.

Shortens duration and reduces severity of symptoms associated with the common cold and throat, nasal, bronchial irritations: cough, headache, hoarseness, sore throat, sinus pressure, chest congestion, nasal congestion, sneezing/runny nose, shrinks swollen nasal membranes, promotes sinus drainage, burning, itchy eyes, helps decongest sinus openings and passages.

Dosage & Administration

Directions

Chew or dissolve tablets in the mouth. Do not swallow whole. For best results, use 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 chewable tablet three times daily.

Children 6-12 of age: Take 1 chewable tablet two times daily.

Children under 6 years of age: Consult a doctor.

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 Doctor

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

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

Keep out of reach of children.

Overdose

In case of overdose, seek medical help or contact a Poison Control center right away.



Add image transcription here...

ALLERGY AND SINUS RELIEF

pelargonium sidoides root, hydrastis canadensis whole, potassium chloride, sanguinaria canadensis root, pulsatilla vulgaris, silicon dioxide tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53499-4194
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]
HYDRASTIS CANADENSIS WHOLE (UNII: R763EBH88T) (HYDRASTIS CANADENSIS WHOLE - UNII:R763EBH88T)	HYDRASTIS CANADENSIS WHOLE	6 [hp_X]
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	3 [hp_X]
SANGUINARIA CANADENSIS ROOT (UNII: N9288CD508) (SANGUINARIA CANADENSIS ROOT - UNII:N9288CD508)	SANGUINARIA CANADENSIS ROOT	6 [hp_X]
PULSATILLA VULGARIS (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	PULSATILLA VULGARIS	6 [hp_X]
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	6 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
CHERRY (UNII: BUC5I9595W)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALIC ACID (UNII: 817L1N4CKP)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MANNITOL (UNII: 3OWL53L36A)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	16mm
Flavor	CHERRY	Imprint Code	C
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499-4194-2	2 in 1 CARTON	08/01/2024	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		08/01/2024	

Labeler - Schwabe North American, Inc. (831153908)

Establishment

Name	Address	ID/FEI	Business Operations
Schwabe North America, Inc.		831153908	manufacture(53499-4194)

Establishment

Name	Address	ID/FEI	Business Operations
Thermo-Pak Company, Inc.		079689440	pack(53499-4194)

Revised: 8/2024

Schwabe North American, Inc.