

**COUGH RELIEF ACONITUM NAPELLUS, BRYONIA ALBA ROOT, CALCIUM SULFIDE, SPONGIA OFFICINALIS SKELETON, ROASTED , TIN, PELARGONIUM SIDOIDES ROOT- cough relief 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.

Cough Relief

Active Ingredients

Pelargonium sidoides 1X

Aconitum napellus 3X

Bryonia 3X

Hepar sulphuris calcareum 6C

Stannum metallicum 6C

Spongia tosta 3X

Inactive Ingredients

Citric Acid

English Ivy Leaf Extract

Ethyl Alcohol

Glycerin

Lactose Monohydrate

Maltodextrin

Potassium Sorbate

Purified Water

Sorbitol

Purpose

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

Temporarily relieves cough due to minor bronchial and throat irritations as may occur with a cold.

Indications & Usage

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

Temporarily relieves cough due to minor bronchial and throat irritations as may occur with a cold.

Doage & Administration

Directions

For best results, use at first sign of symptoms and continue to use for an additional 48 hours after symptoms cease.

Shake well before each use.

Use only with enclosed dosage cup.

Adults and Children 13 years of age and older: Take 1 ½ teaspoons (tsp) (7.5 mL) three times daily.

Children 6 to 12 years of age: Take 1 teaspoon (5 mL) three 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 Genaniaceae 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 a sign of a serious condition.

Overdose

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

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.



Add image transcription here...

COUGH RELIEF ACONITUM NAPELLUS, BRYONIA ALBA ROOT, CALCIUM SULFIDE, SPONGIA OFFICINALIS SKELETON, ROASTED, TIN, PELARGONIUM SIDOIDES ROOT

cough relief syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53499-6864
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
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	3 [hp_X] in 120 mL
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	3 [hp_X] in 120 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	6 [hp_C] in 120 mL
TIN (UNII: 387GMG9FH5) (TIN - UNII:387GMG9FH5)	TIN	6 [hp_C] in 120 mL
SPONGIA OFFICINALIS SKELETON, ROASTED (UNII: 1PIP394IID) (SPONGIA OFFICINALIS SKELETON, ROASTED - UNII:1PIP394IID)	SPONGIA OFFICINALIS SKELETON, ROASTED	3 [hp_X] in 120 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
HEDERA HELIX LEAF (UNII: ZP9XFG71A7)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499-6864-4	1 in 1 BOX	01/19/2024	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/19/2024	

Labeler - Schwabe North America, Inc. (831153908)

Establishment

Name	Address	ID/FEI	Business Operations
Schwabe North America		831153908	manufacture(53499-6864)

Revised: 1/2024

Schwabe North America, Inc.