

**COUGH AND BRONCHIAL NIGHTTIME SYRUP- aconitum napellus, bryonia root, calcium cation, spongia officinalis skeleton, roasted, tin, medicago sativa leaf, oat, arabica coffee bean syrup
Schwabe Mexico S.A. DE C.V.**

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 and Bronchial Nighttime Syrup

Active Ingredient

Acontinum napellus 3X

Alfalfa 1X

Coffea cruda 6X

Avena sativa 1X

Bryonia 3X

Hepar sulphuris calcareum 6C

Spongia tosta 3X

Stannum metallicum 6C

Inactive Ingredient

citric acid

ethyl alcohol

malt extract

purified water

sodium benzoate

sucrose

Dosage & Administration

Directions

Shake well before each use.

Adults & children 12 years of age and older: Take 2 teaspoons (tsp) (10mL) 1/2 hour before bedtime. Dose may be repeated if necessary.

Children under 12 years of age: consult a doctor

Indications & Usage

Temporarily relieves coughs due to minor throat and bronchial irritation occurring with a cold.

Helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes.
Soothes the throat.

Purpose

Temporarily relieves coughs due to minor throat and bronchial irritation occurring with a cold.

Helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes.
Soothes the throat.

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 a 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.

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 last 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 the reach of children

Keep out of the reach of children.

Overdose

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



Add image transcription here...

COUGH AND BRONCHIAL NIGHTTIME SYRUP

aconitum napellus, bryonia root, calcium cation, spongia officinalis skeleton, roasted, tin, medicago sativa leaf, oat, arabica coffee bean syrup

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68466-1009

Route of Administration	ORAL, ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
SPONGIA OFFICINALIS SKELETON, ROASTED (UNII: 1PIP394IID) (SPONGIA OFFICINALIS SKELETON, ROASTED - UNII:1PIP394IID)	SPONGIA OFFICINALIS SKELETON, ROASTED	3 [hp_X] in 120 mL
TIN (UNII: 387GMG9FH5) (TIN - UNII:387GMG9FH5)	TIN	6 [hp_C] in 120 mL
MEDICAGO SATIVA LEAF (UNII: HY3L927V6M) (MEDICAGO SATIVA LEAF - UNII:HY3L927V6M)	MEDICAGO SATIVA LEAF	1 [hp_X] in 120 mL
OAT (UNII: Z6J799EAJK) (OAT - UNII:Z6J799EAJK)	OAT	1 [hp_X] in 120 mL
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	6 [hp_X] in 120 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BARLEY MALT (UNII: R3NBG8914U)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68466-1009-5	1 in 1 CARTON	03/03/2023	
1		120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:68466-1009-9	1 in 1 CARTON	03/03/2023	
2		240 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		03/03/2023	

Labeler - Schwabe Mexico S.A. DE C.V. (812805901)

Establishment

Name	Address	ID/FEI	Business Operations
Schwabe Mexico S.A. DE C.V.		812805901	manufacture(68466-1009)

Revised: 3/2023

Schwabe Mexico S.A. DE C.V.