

COLD FLU RELIEF BERRY CHEWABLE- pelargonium sidoides, aconitum napellus, bryonia, eucalyptus globulus, eupatorium perfoliatum, gelsemium sempervirens, ipecacuanha, phosphorus tablet, chewable 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 + Flu Relief Berry Chewable Tablet

Active Ingredient

PELARGONIUM SIDOIDES 1X

ACONITUM NAPELLUS 4X

EUCALYPTUS GLOBULUS 2X

BRYONIA 4X

EUPATORIUM PERFOLIATUM 6X

GELSEMIUM SEMPERVIRENS 4X

PHOSPHORUS 6X

IPECACUANHA 3X

Inactive Ingredient

ANNATTO SEED EXTRACT COLOR

BEET JUICE COLOR

CARAMEL COLOR

LACTOSE MONOHYDRATE

MAGNESIUM STEARATE

MALIC ACID

MALTODEXTRIN

MANNITOL

NATURAL FLAVOR

SODIUM CROSCARMELLOSE

SORBITOL

STEARIC ACID

XYLITOL

Indications & Usage

Shortens duration and reduces severity of symptoms associated with the common cold and throat/nasal/bronchial irritations, and temporarily relieves flu symptoms: chills/fever, chest congestion, nasal congestion, cough, headache, hoarseness, body aches, sneezing/runny nose, sore throat

Purpose

Shortens duration and reduces severity of symptoms associated with the common cold and throat/nasal/bronchial irritations, and temporarily relieves flu symptoms: chills/fever, chest congestion, nasal congestion, cough, headache, hoarseness, body aches, sneezing/runny nose, sore throat

Dosage and Administration

Directions

Chew or dissolve tablets in the mouth. Do not swallow whole.

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

Adults and children 13 years of age and older: Take 1 chewable tablet 3 times daily.

Children 6-12 years of age: Take 1 chewable tablet 2 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 you are 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.



Offset Print Carton
 Dieline: WCC-2189YS SM
 CMYK MAGENTA YELLOW BLACK UV Gloss
 HS Design update. Matte varnish
 Plate changes: All new.
 Embossing: as LHBN15159.A01. Gloss: New. Matte: as LHBN15144.01
 Proof: Hard copy Prelin-PP0 proof, files sent 9/29/23.
 Turnkey: ThermoPak

Add image transcription here...

COLD FLU RELIEF BERRY CHEWABLE

pelargonium sidoides, aconitum napellus, bryonia, eucalyptus globulus, eupatorium perfoliatum, gelsemium sempervirens, ipecacuanha, phosphorus tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53499-1159
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]
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	4 [hp_X]
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	4 [hp_X]
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6) (EUCALYPTUS GLOBULUS LEAF - UNII:S546YLW6E6)	EUCALYPTUS GLOBULUS LEAF	2 [hp_X]
EUPATORIUM PERFOLIATUM FLOWERING TOP (UNII: 1W0775VX6E) (EUPATORIUM PERFOLIATUM FLOWERING TOP - UNII:1W0775VX6E)	EUPATORIUM PERFOLIATUM FLOWERING TOP	6 [hp_X]
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	4 [hp_X]
IPECAC (UNII: 62I3C8233L) (IPECAC - UNII:62I3C8233L)	IPECAC	3 [hp_X]
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	6 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
ANNATTO (UNII: 6PQP1V1B6O)	
BEET JUICE (UNII: IOZ32L9H3O)	
CARAMEL (UNII: T9D99G2B1R)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALIC ACID (UNII: 817L1N4CKP)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MANNITOL (UNII: 3OWL53L36A)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	pink (pink with pinkish-purple specks)	Score	no score
Shape	ROUND (C)	Size	16mm
Flavor	BERRY (NATURAL BERRY FLAVOR)	Imprint Code	C
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:53499-1159-0	2 in 1 CARTON	07/11/2023	
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		07/11/2023	

Labeler - Schwabe North America, Inc. (831153908)

Establishment

Name	Address	ID/FEI	Business Operations
Schwabe North America, Inc		831153908	manufacture(53499-1159)

Revised: 10/2023

Schwabe North America, Inc.