

COLD RELIEF KIDS CHERRY- pelargonium sidoides 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 Relief Kids Cherry 10 chew tabs

Active Ingredient

Pelargonium sidoides 1X

Inactive Ingredients

Citric Acid

Magnesium Stearate

Malic Acid

Maltodextrin

Mannitol

Natural Flavor

Sodium Croscarmellose

Sorbitol

Stearic Acid

Xylitol

Dosage and 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 years of age: Take 1 chewable tablet two times daily.

Children under 6 years of age: Consult a doctor.

Indications & Usage

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

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

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, 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 reach of children.

Overdose

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



Offset Print Carton
 Die-line: WCC-22231S
 CMYK MAGENTA YELLOW BLACK
 Plate changes: All new.
 Varnish: Satin or Gloss aqueous, still deciding.
 Proof: Hard copy, Prelim/FPD proof, files sent
 Turnkey: ThermoPak

COLD RELIEF KIDS CHERRY			
pelargonium sidoides tablet, chewable			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53499-3351
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]
Inactive Ingredients			

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
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 (CHERRY TABLET)	Score	no score
Shape	ROUND (C)	Size	16mm
Flavor	CHERRY (NATURAL CHERRY FLAVOR)	Imprint Code	C
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499-3351-0	1 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(53499-3351)

Establishment

Name	Address	ID/FEI	Business Operations
Thermo-Pak Company, Inc.		079689440	pack(53499-3351)