

**COLD FLU RELIEF ORANGE- cold flu relief orange 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.*

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**Cold + Flu Relief Orange Chewables**

**Active Ingredients**

Pelargonium sidoides 1X

Aconitum napellus 4X

Eucalyptus globulus 2X

Bryonia 4X

Eupatorium perfoliatum 6X

Gelsemium sempervirens 4X

Phosphorus 6X

Ipecacuanha 3X

**Inactive Ingredients**

Citric Acid

Lactose Monohydrate

Magnesium Stearate

Malic Acid

Maltodextrin

Mannitol

Natural Flavor

Sorbitol

Stearic Acid

Xylitol

**Dosage & 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 & 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, 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.

## **Warnings**

Sore throat warning: if sore throat is severe, persists for 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 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 overdoses, seek medical help or contact a Poison Control Center right away.



## COLD FLU RELIEF ORANGE

cold flu relief orange tablet, chewable

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53499-0161
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Offset Print Carton  
 Dieline: WCC-2189

CYAN	MAGENTA	YELLOW	BLACK	Agessus Gloss Varnish
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HS Design  
 Plate changes: All new.  
 Proof: Pdf. Match colors to approved Prelim MU Proof  
 -LHBN15159.MU

Turkey: ThermoPak

Ingredient Name	Basis of Strength	Strength
<b>PELARGONIUM SIDOIDES ROOT</b> (UNII: H6J53HEX8E) (PELARGONIUM SIDOIDES ROOT - UNII:H6J53HEX8E)	PELARGONIUM SIDOIDES ROOT	1 [hp_X]
<b>ACONITUM NAPELLUS</b> (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	4 [hp_X]
<b>BRYONIA ALBA ROOT</b> (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	4 [hp_X]
<b>EUCALYPTUS GLOBULUS LEAF</b> (UNII: S546YLW6E6) (EUCALYPTUS GLOBULUS LEAF - UNII:S546YLW6E6)	EUCALYPTUS GLOBULUS LEAF	2 [hp_X]
<b>EUPATORIUM PERFOLIATUM FLOWERING TOP</b> (UNII: 1W0775VX6E) (EUPATORIUM PERFOLIATUM FLOWERING TOP - UNII:1W0775VX6E)	EUPATORIUM PERFOLIATUM FLOWERING TOP	6 [hp_X]
<b>GELSEMIUM SEMPERVIRENS ROOT</b> (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	4 [hp_X]
<b>IPECAC</b> (UNII: 62I3C8233L) (IPECAC - UNII:62I3C8233L)	IPECAC	3 [hp_X]
<b>PHOSPHORUS</b> (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	6 [hp_X]

### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALIC ACID</b> (UNII: 817L1N4CKP)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z 65AP)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND (C)	<b>Size</b>	16mm
<b>Flavor</b>	ORANGE (NATURAL ORANGE FLAVOR)	<b>Imprint Code</b>	UMCKA
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499-0161-0	2 in 1 CARTON	06/21/2024	
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		06/21/2024	

**Labeler** - Schwabe North America, Inc. (831153908)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Schwabe North America, Inc.		831153908	manufacture(53499-0161)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Thermo-Pak Company, Inc.		079689440	pack(53499-0161)

Revised: 8/2025

Schwabe North America, Inc.