SAMBUCOL COLD AND FLU RELIEF- bryonia, gelsemium sempervirens, sabucus nigra, sulphur, zincum gluconicum tablet, orally disintegrating PharmaCare US, 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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#### Sambucol Cold and Flu Relief

## **Active Ingredients**

Bryonia 6X

Gelsemium sempervirens 6X, 12X, 30X

Sambucus nigra 3X, 6X

Sulphur 12X

Zincum gluconicum 2X, 6X

## **Purpose**

Bryonia 6XMuscle ache, headache, dry throat, cough
Gelsemium sempervirens 6X, 12X, 30XSneezing
Sambucus nigra 3X, 6XNasal congestion, coughing
Sulphur 12XNasal congestion and pressure, headache
Zincum gluconicum 2X, 6XFatigue, nausea, minor sore throat
* The letters 'HPUS' indicate that the components in this product are officially

<sup>\*</sup> The letters 'HPUS' indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.

#### Uses

- Temporarily relieves cold & flu symptoms.
- Provides temporary relief from respiratory symptoms such as sneezing, runny nose, nasal & sinus congestion, minor sore throat and headache.
- Also temporarily relieves body aches associated with the flu.

# **Warnings**

**Sore throat warning** - Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult physician promptly.

Do not use for children under 4 years of age.

# Stop use and ask a doctor if:

- Symptoms worsen
- Any new symptoms appear
- Fever lasts for more than three days
- Respiratory symptoms persist for more than seven days

**If pregnant or breast feeding,** ask a health professional before use.

**Keep out of the reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

For best results, use at the first sign of symptoms of a cold or flu and continue to use for an additional 48 hours after symptoms subside.

Adults and children 4 years of age and older - Dissolve entire tablet in mouth. Do not chew. Do not swallow whole. Take one tablet at the outset of symptoms. Repeat every three hours.

#### Other Information

Do not use if blister seal is broken

Active ingredients are monographed and microdiluted in accordance with the Homeopathic Pharmacopoeia of the United States.

## **Inactive Ingredients**

Black Carrot Extract (colorant), Croscarmellose Sodium, Elderberry Flavor, Lactose, Magnesium Stearate, Maltodextrin, Microcrystalline Cellulose, Sucrose.

NDC# 52053-0001-4

Sambucol

Black Elderberry

Cold & Flu Relief

90 Count Family Pack

Take at the first sign of cold and flu symptoms

\*\*Temporary relief from:

- Nasal & sinus congestion
- Runny nose
- Sore throat
- Coughing
- Sneezing

90 Tablets

Homeopathic

\*\*Claims based on traditional homeopathic practice, not accepted medical evidence. Not

FDA evaluated.



### SAMBUCOL COLD AND FLU RELIEF

bryonia, gelsemium sempervirens, sabucus nigra, sulphur, zincum gluconicum tablet, orally disintegrating

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Sou	rce)	NDC:5205	3-0001	
Route of Administration	ORAL					
Active Ingredient/Active Moiety						
Ingredient Name			Basis of S	trength	Strength	
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT -			DDVONIA ALD	A DOOT	6 [hp X]	

UNII:T7J046YI2B)	DRIUNIA ALDA KUUI	in 1 mg
SAMBUCUS NIGRA FLOWERING TOP (UNII: CT03BSA18U) (SAMBUCUS NIGRA FLOWERING TOP - UNII:CT03BSA18U)	SAMBUCUS NIGRA FLOWERING TOP	3 [hp_X] in 1 mg
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	6 [hp_X] in 1 mg
ZINC GLUCONATE (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC GLUCONATE	2 [hp_X] in 1 mg
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 1 mg

Inactive Ingredients				
Ingredient Name	Strength			
BLACK CARROT ANTHOCYANINS (UNII: 971DA56IOL)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
EUROPEAN ELDERBERRY JUICE (UNII: Z4IFJ0AK1E)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
SUCROSE (UNII: C151H8M554)				

Product Characteristics				
Color	purple (off purple off grey color with specks)	Score	no score	
Shape	ROUND	Size	10mm	
Flavor	BERRY (Elderberry)	Imprint Code	SCF	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:52053- 0001-4	6 in 1 CARTON	10/15/2021			
1		4500 mg 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		10/15/2021		

# Labeler - PharmaCare US, Inc. (026889965)

Establishment						
Name	Address	ID/FEI	<b>Business Operations</b>			

007306970 manufacture(52053-0001)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ion Labs Inc		106499791	pack(52053-0001)	

PharmaCare US, Inc. Revised: 4/2022