

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.

DRUG FACTS:

ACTIVE INGREDIENTS:

(in Each Tablet): Bryonia 6X,* Gelsemium Sempervirens 6X, 12X, 30X,* Sambucus Nigra 3X, 6X,* Sulphur 12X,* Zincum Gluconicum 2X, 6X.*

*Indicates the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.

PURPOSE:

Bryonia - Muscle ache, headache, dry throat, cough, Gelsemium Sempervirens - Sneezing, Sambucus Nigra - Nasal congestion, coughing, Sulphur - Nasal congestion and pressure, headache, Zincum Gluconicum - Fatigue, nausea, minor sore throat.

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.**

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

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 more than 2 days or administer to children under 3 years of age unless directed by a physician. **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 reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Do not use if blister seal is broken.

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

KEEP OUT OF 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 12 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.

INACTIVE INGREDIENTS:

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

QUESTIONS:

Manufactured exclusively for

Pharmacare US, Inc.

San Diego, CA 92108

SambucolUSA.com or

call 1-888-871-9098

PACKAGE LABEL DISPLAY:

NDC# 52053-0001-2

Sambucol®

BLACK ELDERBERRY

COLD & FLU RELIEF

FAST TEMPORARY RELIEF FROM:

✓ NASAL CONGESTION ✓ SORE THROAT

✓ FEVER + CHILLS ✓ HEADACHE

✓ RUNNY NOSE ✓ COUGH

30 TABLETS

HOMEOPATHIC

FAST TEMPORARY RELIEF FROM:

- NASAL CONGESTION
- SORE THROAT
- FEVER + CHILLS
- HEADACHE
- RUNNY NOSE
- COUGH

30 TABLETS QUICK DISSOLVE HOMEOPATHIC

Quality Guarantee
100% Money Back Guarantee. If you are dissatisfied, and wish to receive a refund, please visit our website for details.

Gluten Free

Drug Facts

Active Ingredients (in Each Tablet):

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Bryonia 6X	Muscle ache, headache, dry throat, cough
Gelsemium sempervirens 6X, 12X, 30X	Sneezing
Sambucus nigra 3X, 6X	Nasal congestion, coughing
Sulphur 12X	Nasal congestion and pressure, headache
Zincum gluconicum 2X, 6X	Fatigue, nausea, minor sore throat

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Adults and children 12 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.

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 (Source)	NDC:52053-0001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BRYONIA ALBA ROOT (UNII: T7J046Y12B) (BRYONIA ALBA ROOT - UNII:T7J046Y12B)	BRYONIA ALBA ROOT	6 [hp_X] in 1 mg
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	6 [hp_X] 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
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 1 mg
ZINC GLUCONATE (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC GLUCONATE	2 [hp_X] in 1 mg

Inactive Ingredients

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

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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52053-0001-2	2 in 1 CARTON	06/30/2017	
1	NDC:52053-0001-1	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		03/26/2013	

Labeler - PharmaCare US, Inc. (026889965)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(52053-0001) , api manufacture(52053-0001) , label(52053-0001) , pack(52053-0001)