

SAMBUCOL COLD AND FLU RELIEF- bryonia, gelsemium sempervirens, sabucus nigra, sulphur, zincum gluconicum tablet
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 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 using.

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.**

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 52053-0004-1

Sambucol

BLACK ELDERBERRY

COLD & FLU RELIEF

FAST TEMPORARY RELIEF FROM:

✓ NASAL CONGESTION ✓ SORE THROAT

✓ FEVER + CHILLS ✓ HEADACHE

✓ RUNNY NOSE ✓ COUGH

60 TABLETS

HOMEOPATHIC

	<p>NDC# 52053-0004-1</p> <h1>Sambucol®</h1> <h2>BLACK ELDERBERRY</h2> <h3>COLD & FLU RELIEF</h3>																
<ul style="list-style-type: none"> With Elderberry and Zinc Unique Homeopathic formulation Quickly dissolves in the mouth without water Great tasting Non-drowsy <p style="text-align: center;"></p> <p style="text-align: center;">HOMEOPATHIC</p>	<p style="text-align: center;">FAST TEMPORARY RELIEF FROM:</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> NASAL CONGESTION</div> <div style="text-align: center;"> SORE THROAT</div> </div> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> FEVER + CHILLS</div> <div style="text-align: center;"> HEADACHE</div> </div> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> RUNNY NOSE</div> <div style="text-align: center;"> COUGH</div> </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;"> <p>60</p> <p>TABLETS</p> </div> <div style="text-align: center;"> </div> <div style="text-align: center;"> <p>QUICK DISSOLVE</p> <p>VALUE PACK</p> </div> </div> <p style="text-align: center;">HOMEOPATHIC</p>	<p style="text-align: center;">Quality Guarantee</p> <p>100% Money Back Guarantee. If you are dissatisfied, and wish to receive a refund, please visit our website for details.</p> <p>Sambucol® is a registered trademark of PharmaCare Laboratories Pty Ltd.</p> <p>Sambucol Cold and Flu Relief is manufactured exclusively for Pharmacare US, Inc. San Diego, CA 92108</p> <p>Made in the USA with domestic and imported ingredients.</p> <p style="text-align: center;">SambucolUSA.com</p> <p style="text-align: center;">or call 1-888-871-9098</p> <p style="font-size: small;">**Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.</p> <p style="text-align: center;">HOMEOPATHIC</p>	<p>Drug Facts</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Active Ingredients (in Each Tablet):</th> <th style="text-align: left;">Purpose</th> </tr> </thead> <tbody> <tr> <td>Bryonia 6X*</td> <td>Muscle ache, headache, dry throat, cough</td> </tr> <tr> <td>Gelsemium sempervirens 6X, 12X, 30X*</td> <td>Sneezing</td> </tr> <tr> <td>Sambucus nigra 3X, 6X*</td> <td>Nasal congestion, coughing</td> </tr> <tr> <td>Sulphur 12X*</td> <td>Nasal congestion and pressure, headache</td> </tr> <tr> <td>Zincum gluconicum 2X, 6X*</td> <td>Fatigue, nausea, minor sore throat</td> </tr> </tbody> </table> <p><small>*Indicates the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.</small></p> <p>Uses**</p> <ul style="list-style-type: none"> ■ 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. <p>Warnings</p> <p>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 physician. Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> ■ Symptoms worsen ■ Any new symptoms appear. ■ Fever lasts for more than three days. ■ Respiratory symptoms persist for more than seven days. <p>If pregnant or breast feeding, ask a health professional before use.</p> <p>Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>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.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Adults and children 12 years of age and older</td> <td style="width: 50%;">Dissolve entire tablet in mouth. Do not chew. Do not swallow whole. Take one tablet at the outset of symptoms. Repeat every three hours.</td> </tr> </table> <p>Other Information ■ Do not use if blister seal is broken</p> <p><small>Active ingredients are monographed and microdilted in accordance with the Homeopathic Pharmacopoeia of the United States.</small></p> <p>Inactive Ingredients Black Carrot Extract (colorant), Croscarmellose Sodium, Elderberry Flavor, Lactose, Magnesium Stearate, Maltodextrin, Microcrystalline Cellulose, Sucrose.</p>	Active Ingredients (in Each Tablet):	Purpose	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	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.
Active Ingredients (in Each Tablet):	Purpose																
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																
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.																

SAMBUCOL COLD AND FLU RELIEF

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52053-0004
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
BLACK CARROT ANTHOCYANINS (UNII: 971DA5610L)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
EUROPEAN ELDERBERRY JUICE (UNII: Z4IFJ0AK1E)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

SUCROSE (UNII: C151H8M554)

MALTODEXTRIN (UNII: 7CVR7L4A2D)

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:52053-0004-1	4 in 1 CARTON	10/04/2021	
1	NDC:52053-0004-2	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		10/04/2021	

Labeler - PharmaCare US, Inc. (026889965)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(52053-0004) , api manufacture(52053-0004) , label(52053-0004) , pack(52053-0004)

Revised: 5/2024

PharmaCare US, Inc.