

**CALMING COMPOSITION- not applicable liquid
Synergy Formulas, 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:

HUMULUS LUPULUS 1X, 3X, VALERIANA OFFICINALIS 1X, 3X, AVENA SATIVA 1X, 6X, 30X, SCUTELLARIA LATERIFLORA 2X, 3X, SUMBUL 3X, MELILOTUS OFFICINALIS 3X, 6X, PASSIFLORA INCARNATA 3X, 6X, PHOSPHORUS 6X, 8X, 12X, IGNATIA AMARA 6X, 12X, MOSCHUS 8X, 10X, ZINCUM METALLICUM 8X, 12X, GLANDULA SUPRARENALIS SUIS 8X, 30X, HYPOTHALAMUS (SUIS) 8X, 30X, PULSATILLA (VULGARIS) 30X, ACONITUM NAPELLUS 30X, 100X, FERULA GLAUCA 6C

INDICATIONS:

Provides temporary relief of tickling cough, troublesome at night. Pains in the joints, and bones. Cramps in calves and soles of feet.

WARNINGS:

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

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

Do not use if tamper evident seal is broken or missing.□

KEEP OUT OF REACH OF CHILDREN:

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

DIRECTIONS:

10 drops orally, 3 times a day. Consult a physician for use in children under 12 years of age.

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INACTIVE INGREDIENTS:

Demineralized Water, 25% Ethanol

QUESTIONS:

Distributed by:

SYNERGY FORMULAS, INC.

251 West Road
Campobello, SC 29322

PACKAGE LABEL DISPLAY:

Synergy Formulas

CALMING COMPOSITION

HOMEOPATHIC

2 FL OZ (60 ml)

<p>DIRECTIONS: 10 drops orally, 3 times a day. Consult a physician for use in children under 12 years of age.</p> <p>WARNINGS: Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. If pregnant or breast-feeding, ask a health professional before use. Do not use if tamper evident seal is broken or missing.</p> <p>LOT: XXXXXX</p> <p>Distributed by: SYNERGY FORMULAS, INC. 251 West Road Campobello, SC 29322</p>	 <p>CALMING COMPOSITION</p> <p>HOMEOPATHIC</p> <p>INACTIVE INGREDIENTS: Demineralized Water, 25% Ethanol 2 FL OZ (60 ml)</p>	<p>ACTIVE INGREDIENTS: Humulus Lupulus 1X, 3X, Valeriana Officinalis 1X, 3X, Avena Sativa 1X, 6X, 30X, Scutellaria Lateriflora 2X, 3X, Sumbul 3X, Melilotus Officinalis 3X, 6X, Passiflora Incarnata 3X, 6X, Phosphorus 6X, 8X, 12X, Ignatia Amara 6X, 12X, Moschus 8X, 10X, Zincum Metallicum 8X, 12X, Glandula Suprarenalis Suis 8X, 30X, Hypothalamus 8X, 30X, Pulsatilla 30X, Aconitum Napellus 30X, 100X, Ferula Glauca 6C.</p> <p>INDICATIONS: Provides temporary relief of tickling cough, troublesome at night. Pains in the joints, and bones. Cramps in calves and soles of feet.</p>
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not applicable liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43772-0044
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOPS (UNII: 01G73H6H83) (HOPS - UNII:01G73H6H83)	HOPS	1 [hp_X] in 1 mL
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	1 [hp_X] in 1 mL
AVENA SATIVA FLOWERING TOP (UNII: MA9CQJ3F7F) (AVENA SATIVA FLOWERING TOP - UNII:MA9CQJ3F7F)	AVENA SATIVA FLOWERING TOP	1 [hp_X] in 1 mL
SCUTELLARIA LATERIFLORA (UNII: 7BP4DH5PDC) (SCUTELLARIA LATERIFLORA - UNII:7BP4DH5PDC)	SCUTELLARIA LATERIFLORA	2 [hp_X] in 1 mL
FERULA SUMBUL ROOT (UNII: GLA4808EHQ) (FERULA SUMBUL ROOT - UNII:GLA4808EHQ)	FERULA SUMBUL ROOT	3 [hp_X] in 1 mL

MELILOTUS OFFICINALIS TOP (UNII: GM6P02J2DX) (MELILOTUS OFFICINALIS TOP - UNII:GM6P02J2DX)	MELILOTUS OFFICINALIS TOP	3 [hp_X] in 1 mL
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O)	PASSIFLORA INCARNATA FLOWERING TOP	3 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	6 [hp_X] in 1 mL
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	6 [hp_X] in 1 mL
MOSCHUS MOSCHIFERUS MUSK SAC RESIN (UNII: 8KFK4W7KP7) (MOSCHUS MOSCHIFERUS MUSK SAC RESIN - UNII:8KFK4W7KP7)	MOSCHUS MOSCHIFERUS MUSK SAC RESIN	8 [hp_X] in 1 mL
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	8 [hp_X] in 1 mL
SUS SCROFA ADRENAL GLAND (UNII: 398IYQ16YV) (SUS SCROFA ADRENAL GLAND - UNII:398IYQ16YV)	SUS SCROFA ADRENAL GLAND	8 [hp_X] in 1 mL
SUS SCROFA HYPOTHALAMUS (UNII: N6R0856Z79) (SUS SCROFA HYPOTHALAMUS - UNII:N6R0856Z79)	SUS SCROFA HYPOTHALAMUS	8 [hp_X] in 1 mL
PULSATILLA VULGARIS (UNII: I76KB35JEV) (PULSATILLA VULGARIS - UNII:I76KB35JEV)	PULSATILLA VULGARIS	30 [hp_X] in 1 mL
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	30 [hp_X] in 1 mL
FERULA COMMUNIS SUBSP. GLAUCA (UNII: 5S9H7NQT11) (FERULA COMMUNIS SUBSP. GLAUCA - UNII:5S9H7NQT11)	FERULA COMMUNIS SUBSP. GLAUCA	6 [hp_C] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43772-0044-1	60 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/17/2014	

Labeler - Synergy Formulas, Inc. (069579220)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43772-0044) , api manufacture(43772-0044) , label(43772-0044) , pack(43772-0044)