

NECK BACK SCIATIC REMEDY- *phytolacca decandra, gnaphalium polycephalum, hypericum perforatum, colocynthis, gelsemium sempervirens, guaiacum, ledum palustre, conium maculatum* lotion
Silver Star Brands

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.

Healthful™ Neck, Back & Sciatic Remedy

HPUS Active Ingredients

HPUS Active Ingredients:** *Phytolacca Decandra* 1X (muscle pain), *Gnaphalium Polycephalum* 3X (intense pain/numbness along nerve), *Hypericum Perforatum* 3X (lower back pain), *Colocynthis* 6X (nerve pain), *Gelsemium Sempervirens* 6X (burning along nerve), *Guaiacum* 6X (neck pain), *Ledum Palustre* 6X (back pain), *Conium Maculatum* 30X (back pain).

**"HPUS" indicates the active ingredients are in the official Homeopathic Pharmacopoeia of the United States.

Uses*

Indications*: May temporarily relieve minor symptoms of back pain and neck discomfort and sharp pain along the sciatic nerve, lower back, and down the back of legs.

*As per various homeopathic materia medicas. These indications have not been evaluated by the FDA, and product has not been clinically tested.

Warnings

Warnings: If symptoms persist or worsen, consult a healthcare professional. If pregnant or breastfeeding, ask a health professional before use. Keep out of reach of children. For external use only. Avoid using near eyes or mouth. If swallowed, get medical help or contact a Poison Control Center immediately. Some individuals may be sensitive to ingredients, if irritation or reaction occurs, discontinue use. Intended to complement, not replace, standard medical care.

Directions

Directions: Apply at least 3 times daily over the affected area. Children under 12 years of age: consult a doctor before use.

Paraben free. No petroleum. No animal testing. No artificial colors or fragrances.

Tamper resistant for your protection. Use only if safety seal is intact.

Inactive Ingredients

Purified Water, Whey Protein Concentrate (milk); Benzyl Alcohol & Ethylhexylglycerin & Tocopherals, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadosensis Leaf Juice, Arnica Montana (Arnica) Flower Extract, Symphytum Officinale (Comfrey) Leaf Extract, *Piscidia Piscipula* (Jamaica Dogwood) Bark Extract, *Phytolacca Americana* (Poke) Root Extract, *Hypericum Perforatum* (St. John's Wort) Aerial Parts Extract, *Salix Alba* (White Willow) Bark Extract, *Achillea Millefolium* (Yarrow) Flower Extract, *Lavandula Angustifolia* (Lavender) Buds Extract, Sodium Hydroxide (solution), Edetate Disodium (EDTA), Ascorbic Acid (Vitamin C powder).

If pregnant or breastfeeding, ask a health professional before use.

Homeopathic Lotion

Indications:** May temporarily relieve minor symptoms of back pain and neck discomfort and sharp pain along the sciatic nerve, lower back, and down the back of legs.

Directions: Apply at least 3 times daily over the affected area. Children under 12 years of age, consult a doctor before use.

Warnings: If symptoms persist or worsen, consult a healthcare professional. If pregnant or breastfeeding, ask a health professional before use. Keep out of reach of children. For external use only. Avoid using near eyes or mouth. If swallowed, get medical help or contact a Poison Control Center immediately. Some individuals may be sensitive to ingredients; if irritation or reaction occurs, discontinue use. Intended to complement, not replace, standard medical care.

*As per various homeopathic materia medicas. These indications have not been evaluated by the FDA, and product has not been clinically tested.

Paraben free. No petroleum. No animal testing. No artificial colors or fragrances. Tamper resistant for your protection. Use only if safety seal is intact.



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Inactive ingredients: Purified Water, Whey Protein Concentrate (milk), Benzyl Alcohol & Ethylhexylglycerin & Tocopherols, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadosensis Leaf Juice, Arnica Montana (Arnica) Flower Extract, Symphytum Officinale (Oonitrey) Leaf Extract, Piscidia Piscipula (Jamaica Dogwood) Bark Extract, Phytolacca Americana (Poke) Root Extract, Hypericum Perforatum (St. John's Wort) Aerial Parts Extract, Salix Alba (White Willow) Bark Extract, Achillea Millefolium (Yarrow) Flower Extract, Lavandula Angustifolia (Lavender) Buds Extract, Sodium Hydroxide (solution), Edetate Disodium (EDTA), Ascorbic Acid (Vitamin C powder).

**HPUS* indicates the active ingredients are in the official Homeopathic Pharmacopoeia of the United States.



NECK BACK SCIATIC REMEDY

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68703-215
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHYTOLACCA AMERICANA ROOT (UNII: 11E6V18VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6V18VEG)	PHYTOLACCA AMERICANA ROOT	1 [hp_X] in 113 g
PSEUDOGNAPHALIUM OBTUSIFOLIUM (UNII: 36XQ854NWW) (PSEUDOGNAPHALIUM OBTUSIFOLIUM - UNII:36XQ854NWW)	PSEUDOGNAPHALIUM OBTUSIFOLIUM	3 [hp_X] in 113 g
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	3 [hp_X] in 113 g
CONIUM MACULATUM FLOWERING TOP (UNII: Q28R5GF371) (CONIUM MACULATUM FLOWERING TOP - UNII:Q28R5GF371)	CONIUM MACULATUM FLOWERING TOP	30 [hp_X] in 113 g
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	6 [hp_X] in 113 g
CITRULLUS COLOCYNTHIS FRUIT (UNII: 0E49E3V9U6) (CITRULLUS COLOCYNTHIS FRUIT - UNII:0E49E3V9U6)	CITRULLUS COLOCYNTHIS FRUIT	6 [hp_X] in 113 g
GUAIAECUM OFFICINALE RESIN (UNII: N0K2Z502R6) (GUAIAECUM OFFICINALE RESIN - UNII:N0K2Z502R6)	GUAIAECUM OFFICINALE RESIN	6 [hp_X] in 113 g
LEDUM PALUSTRE TWIG (UNII: 877L01IZ0P) (LEDUM PALUSTRE TWIG - UNII:877L01IZ0P)	LEDUM PALUSTRE TWIG	6 [hp_X] in 113 g

Inactive Ingredients

Ingredient Name	Strength
PISCIDIA PISCIPULA WHOLE (UNII: ERY1DHL39V)	
PHYTOLACCA AMERICANA FRUIT (UNII: WE63661499)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
COMFREY LEAF (UNII: DG4F8T839X)	
ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA)	
HYPERICUM PERFORATUM FLOWER (UNII: A6V4CUE7PV)	
WHEY (UNII: 8617Z5FMF6)	
WATER (UNII: 059QF0K00R)	

SALIX ALBA BARK (UNII: 205MXS71H7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68703-215-04	113 g in 1 JAR; Type 0: Not a Combination Product	12/11/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/11/2017	

Labeler - Silver Star Brands (006070379)

Registrant - Silver Star Brands (006070379)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(68703-215)

Revised: 3/2018

Silver Star Brands