

ROSACEA - arsenicum alb., arsenicum bromatum, carbo animalis, causticum, hydrocotyle, kali brom., kali iod., kreosotum, lycopodium, nux vom., petroleum, rhus toxicodendron, sepia, sulphur, echinacea, taraxacum liquid
Newton Laboratories, 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.

Rosacea

INDICATIONS & USAGE SECTION

Rosacea Formulated for associated symptoms such as skin changes, discoloration and discomfort of the skin on the face, neck and scalp.

DOSAGE & ADMINISTRATION SECTION

Directions: ORAL USE ONLY - SHAKE WELL. Ages 12 and up, take 6 drops orally (ages 0 to 11, give 3 drops) one to four times daily or as directed by a healthcare professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Arsenicum alb. 10x, Arsenicum bromatum 10x, Carbo animalis 10x, Causticum 10x, Hydrocotyle 10x, Kali brom. 10x, Kali iod. 10x, Kreosotum 10x, Lycopodium 10x, Nux vom. 10x, Petroleum 10x, Rhus toxicodendron 10x, Sepia 10x, Sulphur 10x, Echinacea 3x, Taraxacum 3x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as skin changes, discoloration and discomfort of the skin on the face, neck and scalp.

INACTIVE INGREDIENT SECTION

USP Purified Water; USP Gluten-free, non-GMO, organic cane dispensing alcohol 20%.

QUESTIONS SECTION

www.newtonlabs.net Newton Laboratories, Inc. FDA Est # 1051203 - Conyers, GA 30012
Questions? 1.800.448.7256

WARNINGS SECTION

Warning: Do not use if tamper - evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children

OTC - PREGNANCY OR BREAST FEEDING SECTION

Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

PACKAGE LABEL

www.newtonlabs.net
 Newton Laboratories, Inc. FDA Est # 1051203 • Conyers, GA 30012
Questions? 1.800.448.7256
Warning: Do not use if tamper-evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.



NDC#
55714-2324-1

Rosacea

Formulated for associated symptoms such as skin changes, discoloration and discomfort of the skin on the face, neck and scalp.

1 fl oz (29.57 ml)

Directions: ORAL USE ONLY - SHAKE WELL.
 Ages 12 and up, take 6 drops orally (ages 0 to 11, give 3 drops) one to four times daily or as directed by a healthcare professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

Active Ingredients: Arsenicum alb. 10x, Arsenicum bromatum 10x, Carbo animalis 10x, Causticum 10x, Hydrocotyle 10x, Kali brom. 10x, Kali iod. 10x, Kreosotum 10x, Lycopodium 10x, Nux vom. 10x, Petroleum 10x, Rhus toxicodendron 10x, Sepia 10x, Sulphur 10x, Echinacea 3x, Taraxacum 3x.

Inactive Ingredients: USP Purified water; USP Gluten-free, non-GMO, organic cane dispensing alcohol 20%.

Stock# **N063** Lot#

ROSACEA

arsenicum alb., arsenicum bromatum, carbo animalis, causticum, hydrocotyle, kali brom., kali iod., kreosotum, lycopodium, nux vom., petroleum, rhus toxicodendron, sepia, sulphur, echinacea, taraxacum liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2324
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Arsenic Trioxide (UNII: S7V92P67HO) (Arsenic Cation (3+) - UNII:C96613F5AV)	Arsenic Trioxide	10 [hp_X] in 1 mL
Arsenic Tribromide (UNII: 41CN47507F) (Arsenic Cation (3+) - UNII:C96613F5AV)	Arsenic Tribromide	10 [hp_X] in 1 mL
Carbo Animalis (UNII: 279O8I0433) (Carbo Animalis - UNII:279O8I0433)	Carbo Animalis	10 [hp_X] in 1 mL
Causticum (UNII: DD5FO1WKFU) (Causticum - UNII:DD5FO1WKFU)	Causticum	10 [hp_X] in 1 mL
Centella Asiatica (UNII: 7M867G6T1U) (Centella Asiatica - UNII:7M867G6T1U)	Centella Asiatica	10 [hp_X] in 1 mL
Potassium Bromide (UNII: OSD78555ZM) (Potassium Cation - UNII:295O53K152)	Potassium Bromide	10 [hp_X] in 1 mL
Potassium Iodide (UNII: 1C4QK22F9J) (Iodide Ion - UNII:09G4I6V86Q)	Potassium Iodide	10 [hp_X] in 1 mL
Wood Creosote (UNII: 3JYG22FD73) (Wood Creosote - UNII:3JYG22FD73)	Wood Creosote	10 [hp_X] in 1 mL

Lycopodium Clavatum Spore (UNII: C88X29Y479) (Lycopodium Clavatum Spore - UNII:C88X29Y479)	Lycopodium Clavatum Spore	10 [hp_X] in 1 mL
Strychnos Nux-vomica Seed (UNII: 269XH13919) (Strychnos Nux-vomica Seed - UNII:269XH13919)	Strychnos Nux-vomica Seed	10 [hp_X] in 1 mL
Kerosene (UNII: 1C89KKC04E) (Kerosene - UNII:1C89KKC04E)	Kerosene	10 [hp_X] in 1 mL
Toxicodendron Pubescens Leaf (UNII: 6IO182RP7A) (Toxicodendron Pubescens Leaf - UNII:6IO182RP7A)	Toxicodendron Pubescens Leaf	10 [hp_X] in 1 mL
Sepia Officinalis Juice (UNII: QDL83WN8C2) (Sepia Officinalis Juice - UNII:QDL83WN8C2)	Sepia Officinalis Juice	10 [hp_X] in 1 mL
Sulfur (UNII: 70FD1KFU70) (Sulfur - UNII:70FD1KFU70)	Sulfur	10 [hp_X] in 1 mL
Echinacea, Unspecified (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	3 [hp_X] in 1 mL
Taraxacum Officinale (UNII: 39981FM375) (Taraxacum Officinale - UNII:39981FM375)	Taraxacum Officinale	3 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Alcohol (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2324-1	29.57 mL in 1 BOTTLE, GLASS		
2	NDC:55714-2324-2	59.14 mL in 1 BOTTLE, GLASS		
3	NDC:55714-2324-0	.5 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/01/2011	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	MANUFACTURE(55714-2324)