

**ROSACEA- echinacea, taraxacum officinale, arsenicum album, arsenicum bromatum, carbo animalis, causticum, hydrocotyle asiatica, kali bromatum, kali iodatum, kreosotum, lycopodium clavatum, nux vomica, petroleum, rhus toxicodendron, sepia, sulphur pellet
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 2511P

INDICATIONS & USAGE SECTION

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

DOSAGE & ADMINISTRATION SECTION

Directions: Ages 12 and up, take 6 pellets by mouth (ages 0 to 11, give 3 pellets) one to four times daily or as directed by a health professional. Under age 2, crush/dissolve pellets in purified water. Sensitive persons begin with 1 pellet and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Echinacea 6x, Taraxacum officinale 6x, Arsenicum album 15x, Arsenicum bromatum 15x, Carbo animalis 15x, Causticum 15x, Hydrocotyle asiatica 15x, Kali bromatum 15x, Kali iodatum 15x, Kreosotum 15x, Lycopodium clavatum 15x, Nux vomica 15x, Petroleum 15x, Rhus toxicodendron 15x, Sepia 15x, Sulphur 15x.

OTC - PURPOSE SECTION

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

INACTIVE INGREDIENT SECTION

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

QUESTIONS SECTION

newtonlabs.net – Questions? 800.448.7256

Newton Laboratories, Inc. FDA Est # 1051203 - Conyers, GA 30013

OTC - PREGNANCY OR BREAST FEEDING SECTION

If **pregnant or breast-feeding**, ask a doctor before use.

WARNINGS SECTION

WARNINGS: Keep out of reach of children. Do not use if tamper-evident seal is broken or missing. If symptoms worsen or persist for more than a few days, consult a doctor. If **pregnant or breast-feeding**, ask a doctor before use.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

PACKAGE LABEL

newtonlabs.net ~ Questions? 800.448.7256
 Newton Laboratories, Inc. FDA Est# 1051203 • Conners, GA, 30013
Label statements have not been reviewed by the FDA.

NEWTON homeopathics **Since 1987**

NDC# 55714-2511-1

Rosacea

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

1 OZ (28 G)

Directions: Ages 12 and up, take 6 pellets by mouth (ages 0 to 11, give 3 pellets) one to four times daily or as directed by a health professional. Under age 2, crush/dissolve pellets in purified water. Sensitive persons begin with 1 pellet and gradually increase to full dose.

Active Ingredients: Equal parts of Echinacea 6x, Taraxacum 6x, Arsenicum alb. 15x, Arsenicum brom. 15x, Carbo an. 15x, Causticum 15x, Hydrocotyle 15x, Kali brom. 15x, Kali iod. 15x, Kreosotum 15x, Lycopodium 15x, Nux vom. 15x, Petroleum 15x, Rhus tox. 15x, Sepia 15x, Sulphur 15x.

Inactive Ingredients: Gluten-free, non-GMO, organic beet-derived sucrose (lactose-free) pellets.

Stock# **N063** Lot#

WARNINGS: Keep out of reach of children. Do not use if tamper-evident seal is broken or missing. If symptoms worsen or persist for more than a few days, consult a doctor. If pregnant or breast-feeding, ask a doctor before use.

ROSACEA

echinacea, taraxacum officinale, arsenicum album, arsenicum bromatum, carbo animalis, causticum, hydrocotyle asiatica, kali bromatum, kali iodatum, kreosotum, lycopodium clavatum, nux vomica, petroleum, rhus toxicodendron, sepia, sulphur pellet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2511
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	6 [hp_X] in 1 g
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	15 [hp_X] in 1 g
ARSENIC TRIBROMIDE (UNII: 41CN47507F) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIBROMIDE	15 [hp_X] in 1 g
CARBO ANIMALIS (UNII: 279O8I0433) (CARBO ANIMALIS - UNII:279O8I0433)	CARBO ANIMALIS	15 [hp_X] in 1 g
CAUSTICUM (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)	CAUSTICUM	15 [hp_X] in 1 g
CENTELLA ASIATICA (UNII: 7M867G6T1U) (CENTELLA ASIATICA -	CENTELLA ASIATICA	15 [hp_X]

UNII:7M867G6T1U)	CENTELLA ASIATICA	in 1 g
POTASSIUM BROMIDE (UNII: OSD78555ZM) (BROMIDE ION - UNII:952902IX06)	POTASSIUM BROMIDE	15 [hp_X] in 1 g
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	15 [hp_X] in 1 g
WOOD CREOSOTE (UNII: 3JYG22FD73) (WOOD CREOSOTE - UNII:3JYG22FD73)	WOOD CREOSOTE	15 [hp_X] in 1 g
LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	15 [hp_X] in 1 g
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	15 [hp_X] in 1 g
KEROSENE (UNII: 1C89KKC04E) (KEROSENE - UNII:1C89KKC04E)	KEROSENE	15 [hp_X] in 1 g
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	15 [hp_X] in 1 g
SEPIA OFFICINALIS JUICE (UNII: QDL83WN8C2) (SEPIA OFFICINALIS JUICE - UNII:QDL83WN8C2)	SEPIA OFFICINALIS JUICE	15 [hp_X] in 1 g
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	15 [hp_X] in 1 g
TARAXACUM OFFICINALE (UNII: 39981FM375) (TARAXACUM OFFICINALE - UNII:39981FM375)	TARAXACUM OFFICINALE	6 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2511-1	28 g in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/01/2019	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-2511)