

SUPER SPOT REMOVER ACNE TREATMENT- salicylic acid gel
ORIGINS NATURAL RESOURCES INC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

SUPER SPOT REMOVER™ ACNE TREATMENT

Drug Facts

Active ingredient

Salicylic Acid 1.50%

Purpose

Acne treatment

Uses

- For the treatment of acne

Warnings

For external use only.

Avoid eye area.

Using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.

Keep out of reach of children. If swallowed, call a doctor or contact a Poison Control Center right away.

Directions

- Cleanse skin.
- Apply a thin layer 1 to 3 times daily or as needed.
- If dryness or peeling occurs, reduce application to every other day.

Inactive ingredients

water\aquaeau • alcohol denat. • acrylates/c10-30 alkyl acrylate crosspolymer • hamamelis virginiana (witch hazel) • eugenia caryophyllus (clove) bud oil¹, origanum heracleoticum flower oil¹, eugenol, limonene • cucumis sativus (cucumber) fruit extract • pyrus malus (apple) fruit extract • scutellaria baicalensis root extract • algae extract • poria cocos sclerotium extract • laminaria saccharina extract • lactobacillus ferment • glycerin • caffeine • butylene glycol • tocopheryl acetate • magnesium ascorbyl phosphate • sodium hydroxide • phenoxyethanol <iln37864>

¹ essential oil

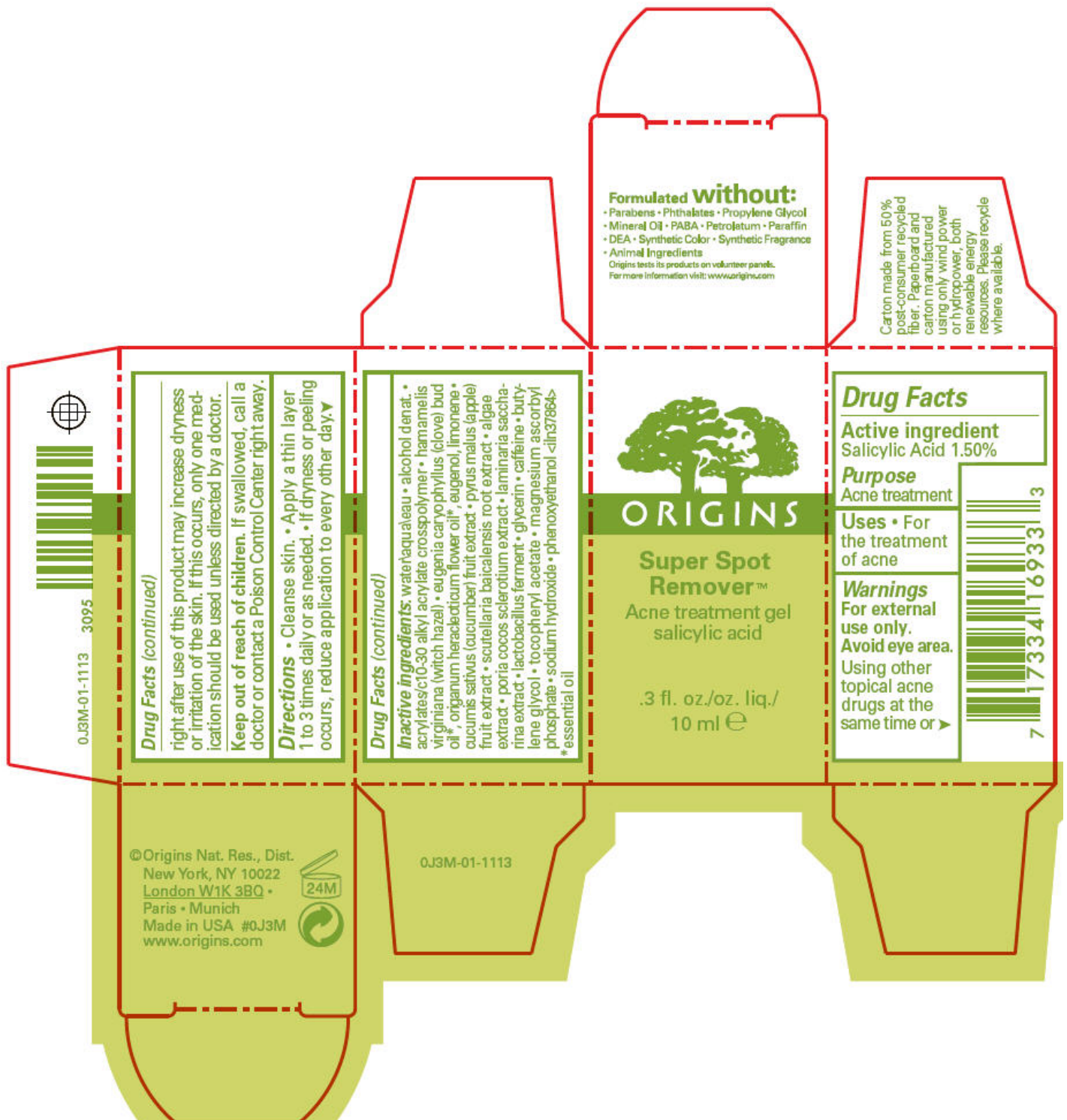
PRINCIPAL DISPLAY PANEL - 10 ml Carton

ORIGINS

Super Spot Remover™

Acne treatment gel
salicylic acid

.3 fl. oz./oz. liq./
10 ml e



SUPER SPOT REMOVER ACNE TREATMENT

salicylic acid gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:59427-005

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)

Basis of Strength

SALICYLIC ACID

Strength

2 mL in 100 mL

Inactive Ingredients

Ingredient Name

Strength

water (UNII: 059QF0KO0R)

witch hazel (UNII: 101I4J0U34)

clove oil (UNII: 578389D6D0)

eugenol (UNII: 3T8H1794QW)

cucumber (UNII: YY7C30VXJT)

apple (UNII: B423VGH5S9)

scutellaria baicalensis root (UNII: 7J95K7ID2S)

saccharina latissima (UNII: 68CMP2MB55)

glycerin (UNII: PDC6A3C0OX)

caffeine (UNII: 3G6A5W338E)

butylene glycol (UNII: 3XUS85K0RA)

.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)

magnesium ascorbyl phosphate (UNII: 0R822556M5)

sodium hydroxide (UNII: 55X04QC32I)

phenoxyethanol (UNII: HIE492ZZ3T)

Packaging

#

Item Code

Package Description

Marketing Start Date

Marketing End Date

1

NDC:59427-005-01

1 in 1 CARTON

1

10 mL in 1 CONTAINER

Marketing Information

Marketing Category

Application Number or Monograph Citation

Marketing Start Date

Marketing End Date

OTC MONOGRAPH FINAL

part333D

04/01/2012

Labeler - ORIGINS NATURAL RESOURCES INC. (611716283)

Establishment

Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(59427-005) , REPACK(59427-005)

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(59427-005) , RELABEL(59427-005) , REPACK(59427-005)

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Inc.		042918826	MANUFACTURE(59427-005)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	REPACK(59427-005) , RELABEL(59427-005)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		253616536	MANUFACTURE(59427-005)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(59427-005)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(59427-005)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(59427-005)

Establishment			
Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(59427-005)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		943871157	MANUFACTURE(59427-005) , RELABEL(59427-005) , REPACK(59427-005)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		959338336	MANUFACTURE(59427-005) , RELABEL(59427-005) , REPACK(59427-005)

Establishment			
Name	Address	ID/FEI	Business Operations

NORTHTEC KEYSTONE		949264774	MANUFACTURE(59427-005) , RELABEL(59427-005) , REPACK(59427-005)
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Establishment			
Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(59427-005)

Establishment			
Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(59427-005)

Establishment			
Name	Address	ID/FEI	Business Operations
Pennsylvania Logistics Center		078364654	REPACK(59427-005) , RELABEL(59427-005)

Revised: 9/2012

ORIGINS NATURAL RESOURCES INC.