

**TREEACTIV CYSTIC ACNE SPOT TREATMENT- sulfur paste**  
**Leiluna LLC**

*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.*

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**TreeActiv Cystic Acne Spot Treatment**

**DRUG FACTS**

**ACTIVE INGREDIENTS**

*Sulfur 3.0%*

*Acne Treatment*

**USE**

*for the treatment of acne.*

**WARNINGS**

**For external use only. Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time. Do not get into eyes. If excessive skin irritation develops or increases, discontinue use and consult a doctor. Apply to affected areas only. Do not use on broken skin or apply to large areas of the body.**

**KEEP OUT OF REACH OF CHILDREN**

**If swallowed, get medical help or contact a Poison Control Center right away.**

**DIRECTIONS**

- **clean the skin thoroughly before applying this product**
- **cover the entire affected area with a thin layer one to three times daily**
- **because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor**
- **if bothersome dryness or peeling occurs, reduce application to once a day or every other day.**

**INACTIVE INGREDIENTS**

**Aqua (Water), Hamamelis Virginiana (Witch Hazel) Water, Bentonite, Alcohol, Leuconostoc/Radish Root Ferment Filtrate, Acacia Senegal Gum, Caprylyl Glycol, Mentha Piperita (Peppermint) Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Citrus Limon (Lemon) Peel Oil, Alcohol Denat., Mentha Piperita (Peppermint) Leaf Extract<sup>1</sup>, Sodium Gluconate, Bisabolol (L-alpha), Dimethicone, Mentha Viridis (Spearmint) Leaf Oil, Citric Acid, Eucalyptus Globulus Leaf Oil, Allantoin, Citrus Paradisi (Pink Grapefruit) Peel Oil, Aloe Barbadensis Leaf Juice Powder<sup>1</sup>**

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<sup>1</sup> Denotes Organic Ingredient

**QUESTIONS?**

**888-201-6444 | [CustomerCare@treeactiv.com](mailto:CustomerCare@treeactiv.com)**

**PRINCIPAL DISPLAY PANEL - 15 ML Jar Box**

TreeActiv

Cystic Acne

Spot Treatment

ACNE TREATMENT

SPOT PASTE

0.5 FL OZ (15ML)

# TreeActiv

## Cystic Acne Spot Treatment

ACNE TREATMENT  
SPOT PASTE

0.5 FL OZ (15ML)






### DRUG FACTS (continued)

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\* Denotes Organic Ingredient

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## Earth Grown Solutions

This Cystic Acne Spot Treatment is a treatment for severe & cystic acne. Packed with all-natural ingredients that calm the skin while helping to clear up acne from within, the treatment is best applied at night before you go to bed. This acne spot treatment should only be applied to areas with a visible blemish as the potent ingredients could overdry clear skin.

**ASSEMBLED IN THE USA**

### DRUG FACTS

#### ACTIVE INGREDIENTS

Sulfur 1.0% ..... Acne Treatment

**USE** for the treatment of acne.

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**DIRECTIONS** • clean the skin thoroughly before applying this product • cover the entire affected area with a thin layer one to three times daily • because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor • if bothersome dryness or peeling occurs, reduce application to once a day or every other day. →

## TREEACTIV CYSTIC ACNE SPOT TREATMENT

sulfur paste

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72841-201
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	30 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	
BENTONITE (UNII: A3N5ZCN45C)	
ALCOHOL (UNII: 3K9958V90M)	
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)	
ACACIA (UNII: 5C5403N26O)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
TEA TREE OIL (UNII: VIF565UC2G)	
LEMON OIL (UNII: I9GRO824LL)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
LEVOMENOL (UNII: 24WE03BX2T)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MENTHA SPICATA OIL (UNII: C3M81465G5)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
ALLANTOIN (UNII: 344S277G0Z)	
GRAPEFRUIT OIL (UNII: YR377U58W9)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72841-201-01	1 in 1 BOX	05/07/2020	
1		15 mL in 1 JAR; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333D	05/07/2020	

**Labeler** - Leiluna LLC (080065214)**Establishment**

Name	Address	ID/FEI	Business Operations
Island Kinetics, Inc. d.b.a. Co Valence Laboratories		959735002	MANUFACTURE(72841-201)

