

SUNDAY RILEY SATURN SULFUR ACNE SPOT TREATMENT MASK- sulfur cream
Sunday Riley Modern Skincare, 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.

SUNDAY RILEY SATURN SULFUR ACNE SPOT TREATMENT MASK

Drug facts

Active Ingredients

Sulfur 10%

Purpose

Acne treatment

Uses

- For the management of acne
- Penetrates pores to control blackheads
- Helps prevent new acne blemishes and blackheads from forming

Warnings

For external use only.

When using this product

- 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
- Apply only to areas with acne

Do not use on

- Broken skin
- Large areas of the skin

Keep out of reach of children.

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

Directions

- Cleanse the skin thoroughly before applying medication.
- For rinse off treatment, apply to dry skin.
- Leave on for 20 minutes and rinse off thoroughly with water.
- For leave-on, overnight treatment, apply to affected area, and rinse off thoroughly in the morning with water.
- Use 2-3 times a week.
- If going outside, use a sunscreen.
- If bothersome dryness or peeling occurs, reduce application use.

Inactive Ingredients

Aqua/Water/Eau, Cetyl Ethylhexanoate, Isoamyl Laurate, Niacinamide, Acacia Senegal Gum, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Bentonite, Leptospermum Scoparium Branch/Leaf Oil, Olive Oil Glycereth-8 Esters, Polyglyceryl-2 Caprate, Zinc PCA, Polysorbate 20, Dipotassium Glycyrrhizate, Allantoin, PEG-40 Hydrogenated Castor Oil, Disodium EDTA, Tocopherols, Denatured Alcohol, Melia Azadirachta Leaf Extract, Amber Powder, Melia Azadirachta Flower Extract, Coccinia Indica Leaf Extract, Ocimum Basilicum (Basil) Flower/leaf Extract, Solanum Melongena (Eggplant) Fruit Extract, Curcuma Longa (Turmeric) Root Extract, Corallina Officinalis Extract, Phenoxyethanol, Caprylyl Glycol, Chlorphenesin, 4-terpineol.

10% Sulfur + 4% Niacinamide + 1% Zinc

Medicated spot treatment mask clears up acne while preventing new blemishes from forming

With Key Ingredients

Sulfur: Absorbs and dries out excess sebum and clarifies the surface of the skin.

Niacinamide: A derivative of Vitamin B3 which promotes clear skin.

Zinc PCA: Helps to balance oil while providing hydration.

Tea Tree and Manuka Oils: Help to clarify the signs of congested skin.

Bentonite: Clay made from volcanic ash, that cleans pores by absorbing dirt and oil.

Formulated with 10% sulfur, this acne-fighting spot treatment mask clears up blemishes and targets causes that lead to future breakouts. High-strength sulfur dries excess (pore-clogging) sebum and removes dead skin cells.

Promoting clearer-looking skin, 4% niacinamide helps boost skin's radiance. Zinc PCA and bentonite help to draw out impurities, reduce excess oil, and soothe the look of surface redness.

Highly potent tea tree oil, standardized for high levels of terpinen-4-ol, partnered with manuka oil, purifies the skin, Complexion looks and feels smoother and clearer with each

use.

DIRECTIONS: Cleanse skin and apply this spot treatment mask to blemished areas. Allow the mask to dry thoroughly before removing with warm water. Can be used several times a week, as needed. sulfur can be drying. If you need hydration after use, apply U.F.O. Acne Treatment Face Oil or Tidal Brightening Enzyme Water Cream.

Made in USA of responsibly sourced domestic and foreign ingredients

Dist/Par: Sunday Riley Modern Skincare, LLC

Houston, TX 77027 USA

EU RP: Obelis s.a., 1030 Brussels, BE

www.sundayriley.com

Packaging

SATURN

SULFUR ACNE
SPOT TREATMENT
MASK

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Drug facts (Continued)

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10% Sulfur +
4% Niacinamide + 1% Zinc

SATURN

SULFUR ACNE
SPOT TREATMENT
MASK

5.00

Medicated spot treatment mask that leads up acne while preventing new blemishes from forming

SUNDAY RILEY

0.5 fl oz

15 mL

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SUNDAY RILEY SATURN SULFUR ACNE SPOT TREATMENT MASK

sulfur cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73001-305
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	0.1 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETYL ETHYLHEXANOATE (UNII: 134647VMX4)	
ISOAMYL LAURATE (UNII: M1SLX00M3M)	
NIACINAMIDE (UNII: 25X51I8RD4)	
ACACIA (UNII: 5C5403N26O)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
BENTONITE (UNII: A3N5ZCN45C)	
MANUKA OIL (UNII: M6QU9ZUH2X)	
OLIVE OIL GLYCERETH-8 ESTERS (UNII: 322K2STO13)	
POLYGLYCERYL-2 CAPRATE (UNII: JX7WXJ41DH)	
ZINC PIDOLATE (UNII: C32PQ86DH4)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
ALLANTOIN (UNII: 344S277G0Z)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALCOHOL (UNII: 3K9958V90M)	
AZADIRACHTA INDICA LEAF (UNII: HKY915780T)	
AMBER (UNII: 70J9Z0J26P)	
AZADIRACHTA INDICA FLOWER (UNII: 3TE8A92UPM)	
COCCINIA GRANDIS LEAF (UNII: YJE89UL5PL)	
OCIMUM BASILICUM FLOWERING TOP (UNII: 7SAB275FP2)	
EGGPLANT (UNII: W5K7RAS4VK)	
TURMERIC (UNII: 856YO1Z64F)	
CORALLINA OFFICINALIS (UNII: 4004498D06)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
4-TERPINEOL, (+/-)- (UNII: L65MV77ZG6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73001-305-15	1 in 1 CARTON	08/31/2020	
1		15 mL in 1 TUBE; 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	08/31/2020	

Labeler - Sunday Riley Modern Skincare, LLC (012302640)

Revised: 11/2021

Sunday Riley Modern Skincare, LLC