

SUNDAY RILEY SULFUR ACNE 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 SULFUR ACNE 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, Bentonite, Niacinamide, Isoamyl Laurate, Cetyl Ethylhexanoate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Olive Oil Glycereth-8 Esters, Polyglyceryl-2 Caprate, Gum Arabic, Sorbitan Isostearate, Polysorbate 60, Zinc PCA, Leptospermum Scoparium (Manuka) Branch/Leaf Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Dipotassium Glycyrrhizate, Allantoin, Quartz, Polysorbate 20, PEG-40 Hydrogenated Castor Oil, Disodium EDTA, Tocopherol, Alcohol Denat., Melia Azadirachta Leaf Extract, Amber Powder, Melia Azadirachta Flower Extract, Coccinia Indica Fruit Extract, Ocimum Basilicum Flower/Leaf Extract, Solanum Melongena Leaf Extract, Curcuma Longa Root Extract, Corallina Officinalis Extract, Phenoxyethanol, Caprylyl Glycol, Chlorphenesin

for acne-prone skin

10% Sulfur + 4% Niacinamide + 1% Zinc

SATURN

Medicated mask dries and clears up acne, while preventing new blemishes from forming

10% sulfur penetrates pores to clear up existing acne while preventing new blemishes from forming. Treats multiple forms of acne breakouts, including blocked pores, inflammatory acne, hormonal acne and acne rosacea.

4% niacinamide promotes clear skin, while boosting skin's healthy-looking radiance. Zinc PCA and bentonite help to clear impurities, reduce excess oil, and soothe the appearance of redness, without overdrying.

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.

Made in USA of responsibly sourced domestic and foreign ingredients

Dist: Sunday Riley Modern Skincare, LLC

Houston, TX 77027

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

www.sundayriley.com

Packaging

OUTER PACKAGE

SATURN
SULFUR ACNE
TREATMENT MASK

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Drug facts (Continued)

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for acne-prone skin
10% Sulfur + 4% Niacinamide + 1% Zinc

48.6

SATURN
SULFUR ACNE
TREATMENT MASK

29.54

Medicated mask dries and clears up acne, while preventing new blemishes from forming

SUNDAY RILEY

2 fl oz 60 ml e

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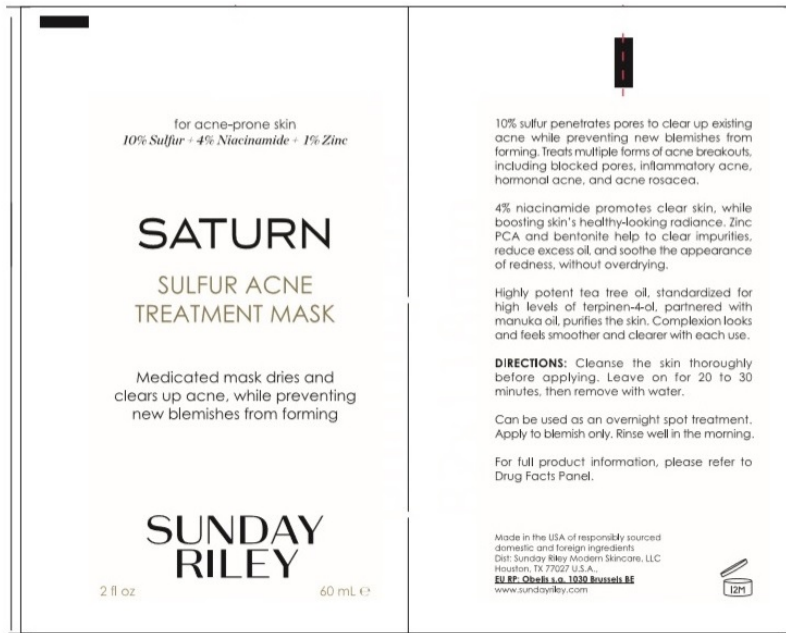
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Highly potent tea tree oil, standardized for high levels of terpinen-4-ol, partnered with manuka oil, purifies the skin. Complexion looks and feels smoother and clearer with each use.

DIRECTIONS: Cleanse your skin thoroughly before applying, then pat dry. Apply Saturn Sulfur Acne Treatment Mask 2 - 3 times per week to acne-prone areas of the skin. Leave on for 20 - 30 minutes, then rinse well with water.





SUNDAY RILEY SULFUR ACNE TREATMENT MASK

sulfur cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73001-340
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)	
BENTONITE (UNII: A3N5ZCN45C)	
NIACINAMIDE (UNII: 25X51I8RD4)	
ISOAMYL LAURATE (UNII: M1SLX00M3M)	
CETYL ETHYLHEXANOATE (UNII: 134647WMX4)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
OLIVE OIL GLYCERETH-8 ESTERS (UNII: 322K2STO13)	
POLYGLYCERYL-2 CAPRATE (UNII: JX7WXJ41DH)	
ACACIA (UNII: 5C5403N26O)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ZINC PIDOLATE (UNII: C32PQ86DH4)	
MANUKA OIL (UNII: M6QU9ZUH2X)	

4-TERPINEOL, (+/-)- (UNII: L65MV77ZG6)
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)
ALLANTOIN (UNII: 344S277G0Z)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
TOCOPHEROL (UNII: ROZB2556P8)
ALCOHOL (UNII: 3K9958V90M)
AZADIRACHTA INDICA LEAF (UNII: HKY915780T)
AMBER (UNII: 70J9Z0J26P)
AZADIRACHTA INDICA FLOWER (UNII: 3TE8A92UPM)
COCCINIA GRANDIS FRUIT (UNII: VLJ6WOT3K5)
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)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73001-340-60	1 in 1 BOX	01/08/2017	
1		60 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	01/08/2017	

Labeler - Sunday Riley Modern Skincare, LLC (012302640)