

ERADIKATE ACNE TREATMENT- sulfur liquid
Kate Somerville 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.

Kate Somerville Skincare - EradiKate Acne Treatment (43479-106)

ACTIVE INGREDIENTS:

SULFUR, 10%

PURPOSE

ACNE TREATMENT

USES

- FOR THE TREATMENT OF ACNE
- HELPS KEEP SKIN CLEAR OF NEW ACNE BLEMISHES

WARNINGS

FOR EXTERNAL USE ONLY

WHEN USING THIS PRODUCT

- USING OTHER TOPICAL ACNE MEDICATION AT THE SAME TIME OR IMMEDIATELY FOLLOWING THE 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.
- AVOID CONTACT WITH EYES. IF EXCESSIVE SKIN IRRITATION DEVELOPS OR INCREASES, DISCONTINUE USE AND CONSULT A DOCTOR.

STOP USE AND ASK A DOCTOR IF SKIN IRRITATION OCCURS.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

- CLEANSE SKIN THOROUGHLY BEFORE APPLYING. COVER THE AFFECTED AREA WITH A THIN LAYER 1 TO 3 TIMES A DAY. BECAUSE EXCESSIVE DRYING OF THE SKIN MAY OCCUR, START WITH 1 APPLICATION DAILY, THEN GRADUALLY INCREASE TO 2 OR 3 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.

OTHER INFORMATION

- DO NOT USE THIS PRODUCT IF YOU HAVE VERY SENSITIVE SKIN OR IF YOU ARE SENSITIVE TO SULFUR.
- YOU MAY REPORT A SERIOUS ADVERSE REACTION FROM USING THIS PRODUCT TO 1-800-981-KATE ON WEEKDAYS 9A.M.-5P.M. PACIFIC TIME.

INACTIVE INGREDIENT

ISOPROPYL ALCOHOL, WATER/AQUA/EAU, CAMPHOR, MAGNESIUM ALUMINUM SILICATE, SALICYLIC ACID, IRON OXIDES (CI 77489, CI 77491, CI 77492, CI 77499), ZINC OXIDE (CI 77947)

<p>EradiKate.® Acne Treatment Traitement Anti-Acné</p> <p>This fast-acting, on-the-spot treatment helps to clear up blemishes and significantly reduces redness. Zinc Oxide absorbs excess sebum production, while Sulfur quickly calms flare-ups and helps prevent future breakouts.</p> <p>Ce traitement local à action rapide supprime les boutons et réduit considérablement les rougeurs. Le camphre élimine les bactéries, l'oxyde de zinc apaise l'irritation et le soufre apaise rapidement et prévient les éruptions.</p> <p>1-800-984-KATE katesomerville.com MADE IN U.S.A./FABRIQUÉ AUX É.-U. This product has not been tested on animals. Ce produit n'a pas été testé sur des animaux. Distr. by/par Kate Somerville Skincare, LLC Beverly Hills, CA 90212 EU Distr. Nantaweg 165, 1043 BW Amsterdam, The Netherlands</p>	<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> • 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 to 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. <p>Inactive Ingredients Isopropyl Alcohol, Water/Aqua/Eau, Camphor, Magnesium Aluminum Silicate, Salicylic Acid, Iron Oxides (CI 77489, CI 77491, CI 77492, CI 77499), Zinc Oxide (CI 77947)</p> <p>Other Information You may report a serious adverse reaction from using this product to 1-800-984-KATE on weekdays 9 a.m. - 5 p.m. PST</p>	<p>Kate Somerville Skin Health Experts.</p> <p>Acne / Peau Acnéique</p> <p>EradiKate.® Acne Treatment Traitement Anti-Acné</p> <p>30 mL 1 Fl. Oz.</p>	<p>Drug Facts</p> <p>Active Ingredients Sulfur 10%</p> <p>Purpose Acne Treatment</p> <p>Uses</p> <ul style="list-style-type: none"> • For the treatment of acne • Helps keep skin clear of new acne blemishes <p>Warnings For external use only.</p> <p>When using this product</p> <ul style="list-style-type: none"> • 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. • apply only to areas with acne. <p>Do not use on</p> <ul style="list-style-type: none"> • broken skin. • large areas of the skin. <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • irritation becomes severe. <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>
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<p>Kate Somerville.®</p> <p>EradiKate.® Acne Treatment Traitement Anti-Acné</p> <p>30 mL 1 Fl. Oz.</p>	<p>Drug Facts</p> <table border="1"> <tr> <td>Active Ingredient</td> <td>Purpose</td> <td>PEEL HERE</td> </tr> <tr> <td>Sulfur 10%</td> <td>Acne Treatment</td> <td></td> </tr> </table> <p>Uses • For the treatment of acne • Helps keep skin clear of new acne blemishes</p> <p>Warnings For external use only.</p> <p>When using this product</p> <ul style="list-style-type: none"> • 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. • apply only to areas with acne. <p>Do not use on</p> <ul style="list-style-type: none"> • broken skin. • large areas of the skin. <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • irritation becomes severe. 	Active Ingredient	Purpose	PEEL HERE	Sulfur 10%	Acne Treatment		<p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>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 to 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.</p> <p>Inactive Ingredients Isopropyl Alcohol, Water/Aqua/Eau, Camphor, Magnesium Aluminum Silicate, Salicylic Acid, Iron Oxides (CI 77489, CI 77491, CI 77492, CI 77499), Zinc Oxide (CI 77947)</p> <p>Other Information • You may report a serious adverse reaction from using this product to 1-800-984-KATE on weekdays 9 a.m. - 5 p.m. PST</p> <p>katesomerville.com MADE IN U.S.A. This product has not been tested on animals. Distributed By Kate Somerville Skincare, LLC Beverly Hills, CA 90212</p>
Active Ingredient	Purpose	PEEL HERE						
Sulfur 10%	Acne Treatment							

ERADIKATE ACNE TREATMENT

sulfur liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43479-106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0KO0R)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
FERROUS OXIDE (UNII: G7036X8B5H)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43479-106-51	1 in 1 BOX	06/15/2014	
1	NDC:43479-106-11	30 mL in 1 BOTTLE, GLASS; 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	06/15/2014	

Labeler - Kate Somerville Skincare, LLC (615155533)

Revised: 1/2022

Kate Somerville Skincare, LLC