

MINERAL BLEMISH KIT- sulfur powder

J. A. Cosmetics U.S. 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.

Active Ingredient:

SULFUR (3%)

Purpose:

ACNE TREATMENT

Uses:

- FOR TREATMENT OF ACNE
- HELPS KEEP SKIN CLEAR OF NEW ACNE BLEMISHES AND ALLOWS SKIN TO HEAL

Warning:

For external use only

When Using This Product

- USING OTHER TROPICAL ACNE MEDICATIONS AT THE SAME TIME OR IMMEDIATELY FOLLOWING USE OF THIS PRODUCT MAY INCREASE DRYNESS OR IRRITATION OF SKIN. IF OCCURS, ONLY ONE MEDICATION SHOULD BE USED UNLESS DIRECTED BY A DOCTOR.

Stop use and ask a doctor if

- rash occurs.

KEEP OUT OF REACH OF CHILDREN.

Directions:

- TAKE THE CONCEALER BRUSH AND DAB INTO THE POWDER. APPLY FORMULA ON AREAS THAT NEED SPOT TREATMENT. USE NIGHTLY TO TREAT AND PREVENT FUTURE BREAKOUTS. AVOID WOUNDS OR ON AREAS OF ECZEMA.

Inactive Ingredient:

MICA, BISMUTH OXYCHLORIDE, ALUMINUM STARCH OCTENYLSUCCINATE, PARAFFINIUM LIQUIDUM (MINERAL OIL), MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL, SODIUM DEHYDROACETATE. MAY CONTAIN: IRON OXIDES (CI 77491, CI 77492, CI 77499)



MINERAL BLEMISH KIT

sulfur powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76354-205
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	3 in 100 g

Inactive Ingredients

Ingredient Name	Strength
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MICA (UNII: V8A1AW0880)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
MINERAL OIL (UNII: T5L8T28FGP)	
TEA TREE OIL (UNII: VIF565UC2G)	
SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76354-205-21	3.3 g in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	10/10/2013	

Labeler - J. A. Cosmetics U.S. INC (186705047)

Registrant - J. A. Cosmetics U.S. INC (186705047)

Establishment

Name	Address	ID/FEI	Business Operations
Shanghai J. A. Cosmetics Trading CO., LTD.		421280183	manufacture(76354-205)

Revised: 3/2014

J. A. Cosmetics U.S. INC