

JACK BLACK CLEARING SPOT TREATMENT- sulfur gel

Jack Black 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.

Jack Black Acne Remedy Clearing Spot Treatment

Active Ingredients

Sulfur 10%

Purpose

Acne Treatment

Uses

- For the treatment of acne
- Dries and clears acne blemishes and blackheads and allows skin to heal.

Warnings

For external use only

When using this product

- apply only to areas with acne
- 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 medication at a time.
- avoid product contact with silver jewelry.

Keep out of reach of children.

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

Do Not Use

- On broken skin
- on large areas of the skin

Directions

- Clean the skin thoroughly before applying this product
- cover the entire area with a thin layer one to three times daily
- Because excess 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

Inactive Ingredients

Water, C12-15 Alkyl Benzoate, Glycerin, Caprylic/Capric Triglyceride, Acacia Senegal Gum, Magnesium Aluminum Silicate, Glyceryl Stearate, PEG-100 Stearate, Pentylene Glycol, Phenoxyethanol, Butylene Glycol, Decylene Glycol, Zinc PCA, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Xanthan Gum, Sodium PCA, Isohexadecane, Ganoderma Lucidum Extract, Sodium Hydroxide, Bisabolol, Ethylhexylglycerin, Polysorbate 80, Lysine, Propanediol, Aloe Barbadensis Leaf Juice, Tetrasodium Glutamate Diacetate, Curcuma Longa (Turmeric) Root Extract, Camellia Sinensis Leaf Extract, 10-Hydroxydecanoic Acid, Sebacic Acid, Magnesium Chloride, Potassium Chloride, Sodium Chloride, 1,10-Decanediol, Zinc Chloride

sulfur gel

Made in USA with US and/or imported ingredients, 01-2348-371

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66738-436
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)		SULFUR	0.5 g in 100 g
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0KO0R)			
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPANEDIOL (UNII: 5965N8W85T)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
CURCUMA LONGA WHOLE (UNII: W5488JUO8U)			
CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)			
ALOE (UNII: V5VD430YW9)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
ACACIA SENEGAL FLOWER (UNII: 72P931MTC2)			
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)			
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)			
PEG-100 STEARATE (UNII: YD01N1999R)			
PENTYLENE GLYCOL (UNII: 50C1307PZG)			
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
DECYLENE GLYCOL (UNII: S57M60MI88)			
ZINC PIDOLATE (UNII: C32PQ86DH4)			
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)			
XANTHAN GUM (UNII: TTV12P4NEE)			
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)			
ISOHEXADECANE (UNII: 918X1OUF1E)			
GANODERMA LUCIDUM WHOLE (UNII: J5P04QW0CF)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			
LEVOMENOL (UNII: 24WE03BX2T)			
POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
LYSINE (UNII: K3Z4F929H6)			
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)			
10-HYDROXYDECANOIC ACID (UNII: NP03XO416B)			
SEBACIC ACID (UNII: 97AN39ICTC)			
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)			
POTASSIUM CHLORIDE (UNII: 660YQ98I10)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
1,10-DECANEDIOL (UNII: 5I577UDK52)			
ZINC CHLORIDE (UNII: 86Q357L16B)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66738-436-01	1 in 1 CARTON	02/12/2021	
1		15 g 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	M006	02/12/2021	

Labeler - Jack Black LLC (847024036)

Revised: 11/2022

Jack Black LLC