EPIONCE PURIFYING SPOT GEL- sulfur gel
Episciences, 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.

Epionce Purifying Spot Gel

Active ingredients

Sulfur 3.3%

Purpose

Acne Treatment

Use

- For the treatment of acne

Warnings

For external use only

When using this product

- skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, use only one topical acne medication at a time
- apply only to areas with acne
- rinse right away with water if it gets in eyes.

Do not use on

- broken skin
- large areas of skin

Stop use and ask a doctor

- if skin irritation occurs or gets worse

Keep out of reach of children.

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

Directions

- clean the skin thoroughly before applying this product
- cover 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 gradulally increase to two or three times daily if needed or as directed by a doctor

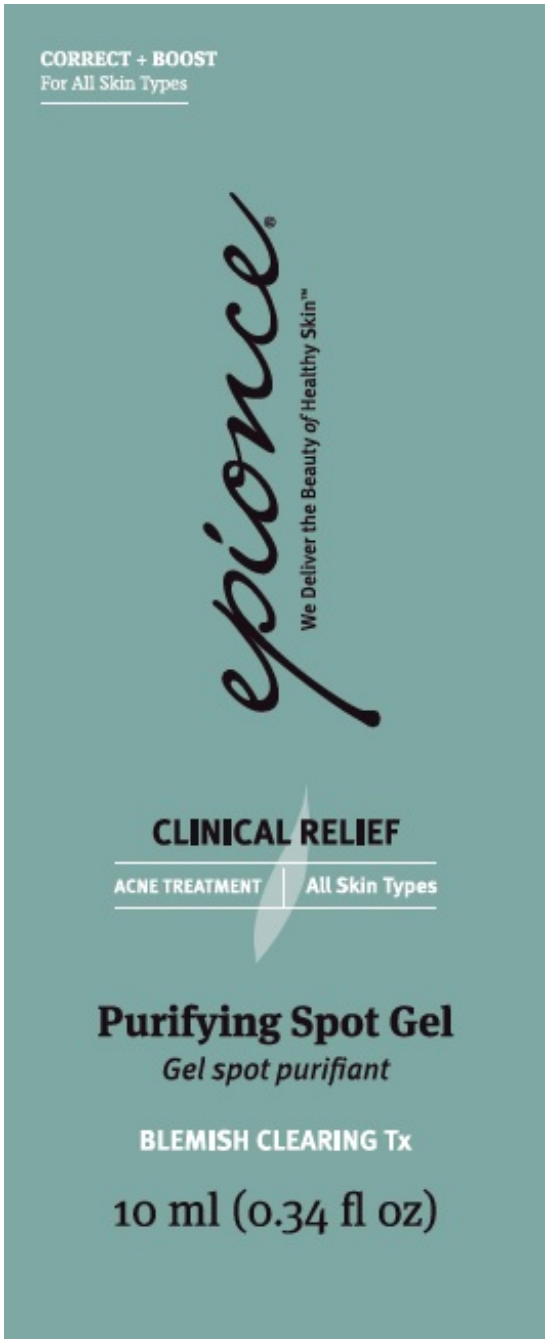
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day

Inactive ingredients

Azelaic Acid, Butylene Glycol, Caprylyl Glycol, Coconut Oil, Ethylhexylglycerin, Glycerin, Helianthus Annuus Flowering Top, Hexylene Glycol, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (100000 MPA.S AT 1.5%), Levomenthol, Medium-Chain Triglycerides, Orange Oil, Paprika, Phenoxyethanol, Pyrithione Zinc, Quercetin, Resorcinol Monoacetate, Rice Bran, Rosemary, Safflower Oil, Spearmint Oil, Sulfur, Tocopherol, Water

Questions?

Call toll free **1-866-374-6623**



EPIONCE PURIFYING SPOT GEL

sulfur gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:42673-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	0.033 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
RICE BRAN (UNII: R60QEP13IC)	
ROSEMARY (UNII: IJ67X351P9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ORANGE OIL (UNII: AKN3KSD11B)	
PAPRIKA (UNII: X72Z47861V)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PYRITHIONE ZINC (UNII: R953O2RHZ5)	
AZELAIC ACID (UNII: F2VW3D43YT)	
GLYCERIN (UNII: PDC6A3C0OX)	
QUERCETIN (UNII: 9IKM0I5T1E)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
TOCOPHEROL (UNII: R0ZB2556P8)	
WATER (UNII: 059QF0KO0R)	
RESORCINOL MONOACETATE (UNII: YL6O37RD1S)	
SPEARMINT OIL (UNII: C3M81465G5)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42673-007-01	1 in 1 BOX	10/02/2018	05/31/2024
1	NDC:42673-007-00	10 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	part333D	10/02/2018	05/31/2024

Labeler - Episciences, Inc. (144733040)

Establishment

Name	Address	ID/FEI	Business Operations
Episciences, Inc.		144733040	manufacture(42673-007)