REZAMID- sulfur and resorcinol lotion
Summers Laboratories 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 5%

RESORCINOL 2%

PURPOSE

ACNE TREATMENT LOTION

USE

DRIES UP ACNE PIMPLES, HELPS PREVENT NEW PIMPLES

WARNINGS
- FOR EXTERNAL USE ONLY

DO NOT USE
- ON BROKEN SKIN
- ON LARGE AREAS OF THE BODY

WHEN USING THIS PRODUCT
- APPLY TO AFFECTED AREAS ONLY
- DO NOT GET INTO EYES
- 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

STOP USE AND ASK A DOCTOR IF
- IF SKIN IRRITATION OCCURS OR GETS WORSE

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

Directions
- shake very well before using
- 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 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

water, SD-40 alcohol 28%, zinc oxide, talc, titanium dioxide, propylene glycol, attapulgite, lauramide DEA, iron oxides, sodium bisulfite, PEG-8 laurate, parachlorometaxylenol, hydroxyethylcellulose, sodium chloride, sodium polynapthalene sulfonate, EDTA, methyl paraben, xanthan gum, butylparaben, fragrance, simethicone.

REZAMID

sulfur and resorcinol lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11086-022
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	5 g in 100 mL
RESORCINOL (UNII: YUL4LO94HK) (RESORCINOL - UNII:YUL4LO94HK)	RESORCINOL	2 in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	28 mL in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ATTAPULGITE (UNII: U6V729APAM)	
LAURIC DIETHANOLAMIDE (UNII: I29I2VHG38)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM BISULFITE (UNII: TZX5469Z6I)	
PEG-8 LAURATE (UNII: 762O8IWA10)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM NAPHTHALENESULFONATE (UNII: D3F8YRX7TP)	
EDETIC ACID (UNII: 9G34HU7RV0)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON (UNII: Z4152N8IUI)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11086-022-11	1 in 1 BOX		
1	NDC:11086-022-01	56.7 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	10/30/2013	

Labeler - Summers Laboratories Inc (002382612)

Establishment

Name	Address	ID/FEI	Business Operations
Summers Laboratories Inc		002382612	manufacture(11086-022) , pack(11086-022)

Revised: 10/2014 Summers Laboratories Inc