CLARIFYING MASK-sulfur and resorcinol paste Halogent, LLC (DBA Exposed Skin Care)

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.

PURPOSE

ACNE TREATMENT

ACTIVE INGRDIENT

SULFUR (3.0%)

RESORCINOL (2.0%)

USE

FOR THE TREATMENT OF ACNE

WARNINGS FOR EXTERNAL USE ONLY

When using this product

- using other topical acne medications at the same time or immediately following the use of this product may increase dryness or irritation. If this occurs, only one medication should be used unless directed by a doctor
- apply only to areas with acne
- do not get into eyes
- do not use on broken skin or large areas of the skin

Stop use and ask a doctor if

SKIN IRRITATION OCCURS OR GET WORSE

Directions

Use 1 to 2 times per week

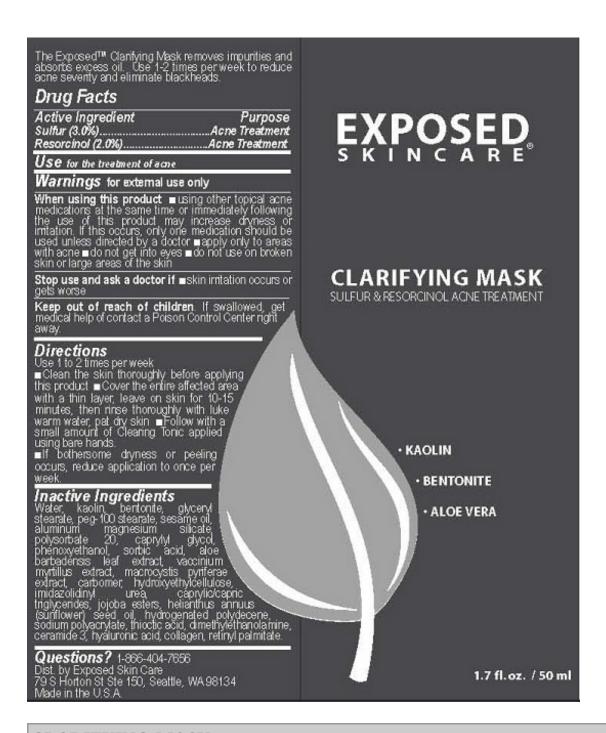
- Clean the skin thoroughly before applying this product
- Cover the entire affected area with a thin layer, leave on skin for 10-15 minutes, then rinse thoroughly with luke warm water, pat dry skin
- Follow with a small amount of Clearing Tonic applied using bare hands.
- If bothersome dryness or peeling occurs, reduce application to once per week.

Inactive Ingredients

Water, kaolin, bentonite, glyceryl stearate, peg-100 stearate, sesame oil, aluminum magnesium silicate, polysorbate 20, caprylyl glycol, phenoxyethanol, sorbic acid, aloe barbadensis leaf extract, vaccinium myrtillus extract, macrocystis pyriferae extract, carbomer, hydroxyethylcellulose, imidazolidinyl urea, caprylic/capric triglycerides, jojoba esters, helianthus annuus (sunflower) seed oil, hydrogenated polydecene, sodium polyacrylate, thioctic acid, dimethylethanolamine, ceramide 3, hyaluronic acid, collagen, retinyl palmitate.

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

Questions? 1-866-404-7656



CLARIFYING MASK

sulfur resorcinol paste

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:55878-102
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SULFUR (SULFUR)	SULFUR	3 g in 100 mL		
RESORCINOL (RESORCINOL)	RESORCINOL	2 g in 100 mL		

Inactive Ingredients		
Ingredient Name	Strength	
WATER		
KAOLIN		
BENTONITE		
GLYCERYL MONOSTEARATE		
PEG-100 STEARATE		
SESAME OIL		
MAGNESIUM ALUMINUM SILICATE		
POLYSORBATE 20		
CAPRYLYL GLYCOL		
PHENOXYETHANOL		
SORBIC ACID		
ALOE VERA LEAF		
VACCINIUM MYRTILLUS WHOLE		
MACRO CYSTIS PYRIFERA		
CARBOMER 940		
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%)		
IMIDUREA		
MEDIUM-CHAIN TRIGLYCERIDES		
JOJOBA OIL		
SUNFLO WER O IL		
HYDRO GENATED POLYDECENE (550 MW)		
SODIUM POLYACRYLATE (8000 MW)		
THIO CTIC ACID, (+)-		
DEANOL		
CERAMIDE 3		
HYALURO NIC ACID		
COLLAGEN, SOLUBLE, FISH SKIN		
VITAMIN A PALMITATE		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:55878-102-12	50 mL in 1 TUBE		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part333D	02/07/2013			

Labeler - Halogent, LLC (DBA Exposed Skin Care) (790961697)

Revised: 2/2013