X OUT SPOT CORRECTOR- sulfur lotion Guthy-Renker 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.

X[®] Out Spot Corrector

Drug Facts

Active ingredient

Sulfur 6%

Purpose

Acne treatment

Use

for the management of acne.

Warnings

For external use only

When using this product

- skin irritation and dryness are 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.
- apply only to areas with acne.

Do not use on

- broken skin
- large areas of the skin

Stop use and ask a doctor

If irritation becomes severe.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply a small amount to dampened skin.
- cover the entire affected area with a thin layer <u>and rinse thoroughly</u> 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.
- *Sensitivity Test for a New User:* Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions above.

Inactive ingredients

water, dicaprylyl carbonate, montmorillonite, alcohol denat., neopentyl glycol diheptanoate, glycerine, acacia senegal gum, triethanolamine, olive oil PEG-7 esters, butylene glycol, ethoxydiglycol, camellia sinensis leaf extract, cymbopogon schoenanthus extract, geranium maculatum extract, melaleuca alternifolia (tea tree) leaf oil, dipotassium glycyrrhizate, hydroxyphenyl propamidobenzoic acid, tocopheryl acetate, allantoin, pentylene glycol, ethylhexylglycerin, butyl oleate, glyceryl acrylate/acrylic acid copolymer, acrylates/C10-30 alkyl acrylate crosspolymer, disodium EDTA, butylparaben, ethylparaben, isobutylparaben, methylparaben, phenoxyethanol, propylparaben, fragrance

Questions or comments?

Within US 1-800-524-7952

Dist. by: Guthy-Renker® LLC • PO Box 14383 Palm Desert, CA 92255-4383

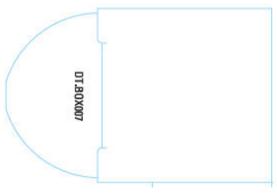
PRINCIPAL DISPLAY PANEL - 30 mL Tube Carton

X® OUT

SPOT CORRECTOR

From the Makers of Proactiv®

sulfur acne treatment 1.0 FL. OZ. • 30 mL



Drug Facts (continued)

EDTA, butyparaben, ethyparaben, isobutyparaben, methyparaben, propyparaben, fragrance (parfum) acid copolymer, acrylates/C10-30 alkyl acrylate crosspolymer, disodium pentylene glycol, ethylhexylglycenn, butyl oleate, glyceryl acrylate/acrylic hydroxyphenyl propamidobenzoic acid, tocopheryl acetate, allantoin,

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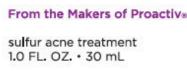
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sulfur acne treatment

SPOT CORRECTOR

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Drug Facts

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Use for the management of acne

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skin irritation and dryness are more likely to occur if you use another

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Drug Facts (continued)

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daily if needed or as directed by a doctor.

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Directions

Drug Facts (continued)

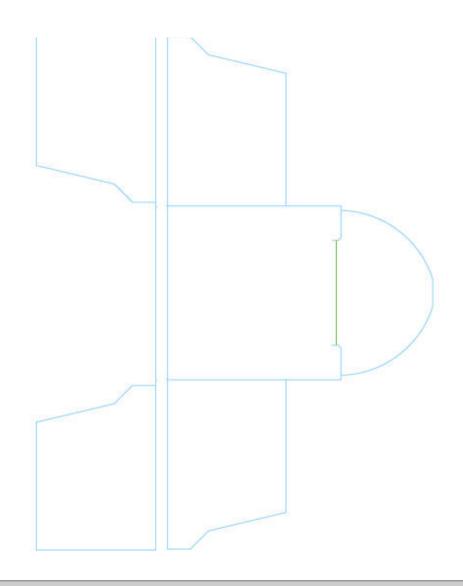
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X OUT SPOT CORRECTOR

sulfur lotion

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:11410-006
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SULFUR (SULFUR)	SULFUR	6 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER	
DICAPRYLYL CARBONATE	
MONTMORILLONITE	
ALCOHOL	
NEO PENTYL GLYCOL DIHEPTANO ATE	

GLYCERIN	
ACACIA	
TROLAMINE	
BUTYLENE GLYCOL	
DIETHYLENE GLYCOL MONOETHYL ETHER	
GREEN TEA LEAF	
CYMBOPOGON SCHOENANTHUS TOP	
GERANIUM MACULATUM ROOT	
TEA TREE OIL	
GLYCYRRHIZINATE DIPO TASSIUM	
HYDRO XYPHENYL PRO PAMIDO BENZO IC ACID	
.ALPHATO COPHEROL ACETATE	
ALLANTOIN	
PENTYLENE GLYCOL	
ETHYLHEXYLGLYCERIN	
BUTYL OLEATE	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)	
EDETATE DISO DIUM	
BUTYLPARABEN	
ETHYLPARABEN	
ISOBUTYLPARABEN	
METHYLPARABEN	
PHENO XYETHANO L	
PROPYLPARABEN	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11410-006-11	1 in 1 BOX		
1		30 mL in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part333D	12/31/2012		

Labeler - Guthy-Renker LLC (608315453)

Revised: 1/2013 Guthy-Renker LLC