

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 and rinse thoroughly 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



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Drug Facts (continued)

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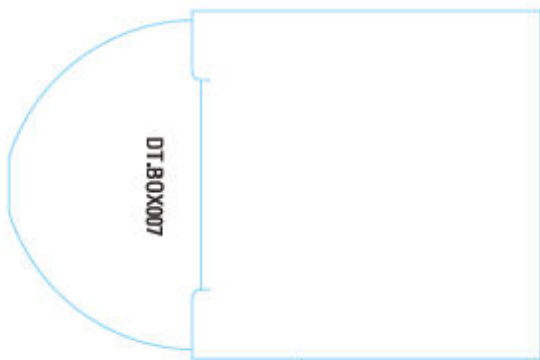
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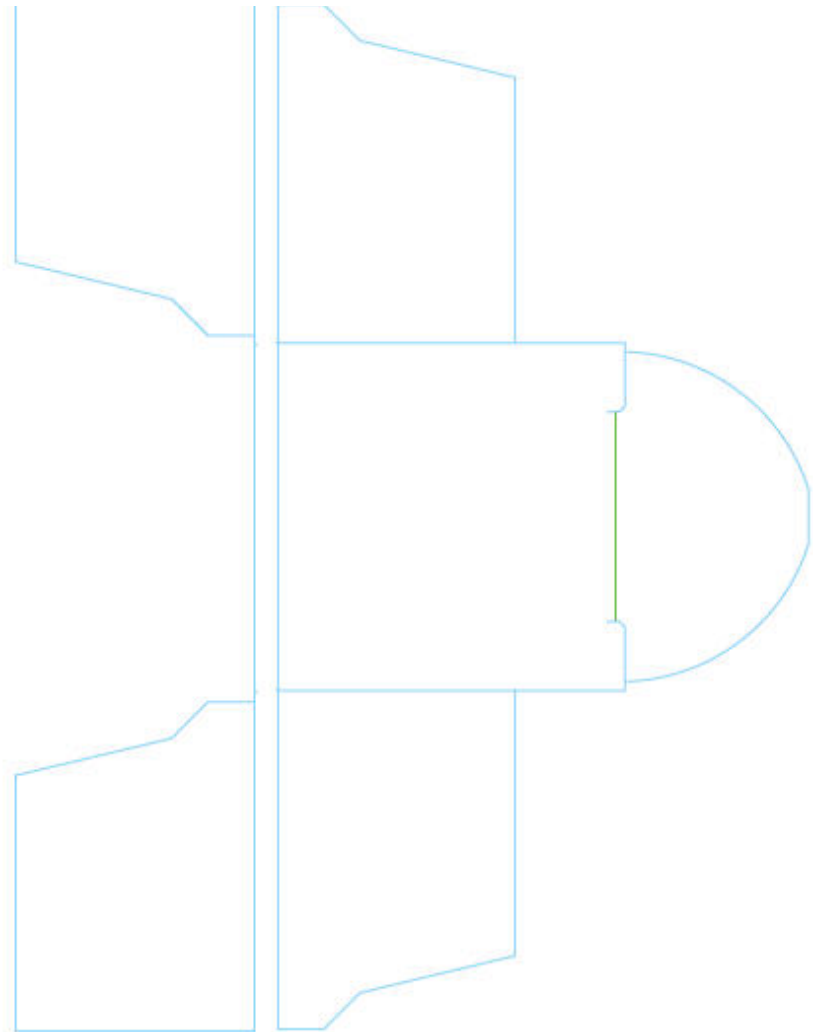
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Drug Facts (continued)

melaleuca alternifolia (tea tree) leaf oil, dipotassium glycyrrhizate, hydroxyphenyl propamidobenzoic acid, tocopheryl acetate, allantoin, pentylene glycol, ethylhexylglycerin, butyl ceteate, glyceryl acrylate/acrylic acid copolymer, acrylates/C10-30 alkyl acrylate crosspolymer, disodium EDTA, butylparaben, ethylparaben, isobutylparaben, methylparaben, phenoxyethanol, propylparaben, fragrance (parfum)
Questions or comments? Within US 1-800-524-7952
Dist. by: Guthy-Renker® LLC • PO Box 14383 Palm Desert, CA 92256-1383 • XDur.com/reorder
Made in the USA or Foreign and Domestic Components
XOut is a trademark in the United States and may be a trademark in other countries.





X OUT SPOT CORRECTOR

sulfur lotion

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	6 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
MONTMORILLONITE (UNII: A585MN1H2L)	
ALCOHOL (UNII: 3K9958V90M)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	

GLYCERIN (UNII: PDC6A3C0OX)
ACACIA (UNII: 5C5403N26O)
TROLAMINE (UNII: 9O3K93S3TK)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
CYMBOPOGON SCHOENANTHUS TOP (UNII: 9SJ11LW39W)
GERANIUM MACULATUM ROOT (UNII: 93IXI5B6OJ)
TEA TREE OIL (UNII: VIF565UC2G)
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)
HYDROXYPHENYL PROPAMIDOBENZOIC ACID (UNII: 25KRT26H77)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ALLANTOIN (UNII: 344S277G0Z)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
BUTYL OLEATE (UNII: 487I65419Q)
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)
EDETATE DISODIUM (UNII: 7FLD91C86K)
BUTYLPARABEN (UNII: 3QPIIU3FV8)
ETHYLPARABEN (UNII: 14255EXE39)
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)
METHYLPARABEN (UNII: A2I8C7HI9T)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
PROPYLPARABEN (UNII: Z8IX2SC1OH)

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)