ISOMERS CLEAR SKIN ACNE SPOT TREATMENT - salicylic acid gel Isomers 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.

DRUG FACTS

Enter section text here

Active Ingredient:

Salicylic Acid 2%

Enter section text here

Purpose:

Acne Treatment

Enter section text here

Stop use and ask doctor

If irritation becomes severe

Enter section text here

Keep out of reach of children

Enter section text here

Warnings:

- For external use only
- Keep away from eyes
- Using other topical acne medications at the same time or immediately following the use of this product may increase dryness or irritation of the skin, if this occurs only one medication should be used.
- In case of accidental ingestion seek professional assistance or contact a poison control center immediately

Enter section text here

Inactive Ingredients:

Purified Water, Propylene Glycol, Optunia Ficus Indica Stem Extract, Boerhavia Diffusa root Extract, Thermus Thermophilus Ferment, Glycerin, Pentylene Glycol, Zinc PCA, Hydroxyethyl Cellulose, Phenoxyethanol, Decylene Glycol, Sodium Stearoyl Lacylate, Sodium Hydroxide.

CSAST30.jpg

ISOMERS®

clear skin acne spot treatment gel

30 ml / 1.01 fl oz

ISOMERS CLEAR SKIN ACNE SPOT TREATMENT GEL Drug Facts

Active Ingredient Purpose
Salicylic Acid 2% Acne Treatment

Uses: Treats Acne

Warning For External use only. Keep away from eyes. Using other topical acne medications at the same time or immediately following the use of this product may increase dryness or irritation of the skin, if this occurs only one medication should be used. Stop use and ask a doctor if irritation becomes severe. In case of accidental ingestion seek professional assistance or contact a poison control center immediately. Keep out of reach of children

Directions Cleanse the skin thoroughly before applying medication. Apply as a spot treatment on the acne pimples and leave on, can be used up to three times daily. Avoid contact with eyes

Inactive ingredients Purified water, Propylene Glycol, Optunia Ficus Indica Stem Extract, Boerhavia Diffusa root Extract, Thermus Thermophilus Ferment, Glycerin, Pentylene Glycol, Zinc PCA, Hydroxyethyl Cellulose, Phenoxyethanol, Decylene Glycol, Sodium Stearoyl Lactylate, Sodium Hydroxide.

Manufactured by

Isomers Laboratories Inc Toronto, Ontario Canada M6B 1W3 Phone: 416.787.2465 www.isomers.ca Made in Canada

Lot No. Exp.

ISOMERS CLEAR SKIN ACNE SPOT TREATMENT

salicylic acid gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:64990-601

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)
SALICYLIC ACID (0.02 mL in 1 mL

Ingredient Name Strength WATER (UNII: 059QF0KO0R) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) OPUNTIA FICUS-INDICA (UNII: 23Z87HTQ6P) GLYCERIN (UNII: PDC6A3C0OX) HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16) PHENOXYETHANOL (UNII: HIE492ZZ3T) SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:64990-601-04	30 mL in 1 BOTTLE					

Marketing	Information
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Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date

OTC monograph final	part333D	03/01/2010	

Labeler - Isomers Laboratories Inc (253306799)

Registrant - Isomers Laboratories Inc (253306799)

Establishment						
Name	Address	ID/FEI	Business Operations			
Isomers Laboratories Inc		253306799	manufacture			

Revised: 3/2010 Isomers Laboratories Inc