

ISOMERS CLEAR SKIN ACNE TREATMENT GEL - 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

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ACTIVE INGREDIENT

Salicylic Acid 2%

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

PURPOSE

ACNE TREATMENT

Enter section text here

WARNINGS

- For External Use Only
- Keep away from eyes
- Using other topical 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 advice 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 Lactate, Sodium Hydroxide

Enter section text here

ISOMERS[®]

clear skin
acne treatment gel

60 ml / 2.03 fl oz

ISOMERS CLEAR SKIN ACNE 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. Cover the entire affected area with a thin layer 1 to 3 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
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Toronto, Ontario Canada M6B 1W3
Phone: 416.787.2465 www.isomers.ca
Made in Canada

Lot No.
Exp.

ISOMERS CLEAR SKIN ACNE TREATMENT GEL

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	Strength
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	0.02 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Glycerin (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Sodium Hydroxide (UNII: 55X04QC32I)	
OPUNTIA FICUS-INDICA (UNII: 23Z87HTQ6P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64990-601-01	60 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	12/26/2009	

Labeler - Isomers Laboratories Inc (253306799)

Registrant - Isomers Laboratories Inc (253306799)

Establishment

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

Revised: 1/2010

Isomers Laboratories Inc