ISOMERS CLEAR SKIN ACNE TREATMENT LOTION - salicylic acid lotion 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

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, Cetearyl Alcohol, Ceteth-20 Phosphate, Dicetyl Phosphate, Caprylic/Capric Triglyceride, Glycerin, Cetyl Alcohol, C 10-30 Cholesterol Lanosterol Esters, Optunia Ficus Indica Stem Extract, Boerhavia Diffusa Root Extract, Thermus Thermophilus Ferment, Pentylene Glycol, Phenoxyethanol, Tropolone, Decylene Glycol, C 20-40 Pareth-10, Zinc PCA, Sodium Hydroxide.

CSATL60.jpg



clear skin acne treatment Lotion

ISOMERS CLEAR SKIN ACNE TREATMENT LOTION

Drug Facts

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, Cetearyl Alcohol, Ceteth 20 Phosphate, Dicetyl Phosphate, Caprilic/capric Triglyceride, Glycerin, Cetyl alcohol, C10-30 Cholesterol Lanosterol Esters, Optunia Ficus Indica Stem Extract, Boerhavia Diffusa Root Extract, Thermus Thermophilus Ferment, Pentylene Glycol, Phenoxyethanol, Tropolone, Decylene Glycol, C20-40 Pareth-10, Zinc PCA, Sodium Hydroxide.

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

Lot No. Exp.

60 ml / 2.03 fl oz

ISOMERS CLEAR SKIN ACNE TREATMENT LOTION

salicylic acid lotion

| Product Information | | | |
|----------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:64990-605 |
| 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) | | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | | |
| DIHEXADECYL PHO SPHATE (UNII: 2V6E5WN99N) | | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | | |
| O PUNTIA FICUS-INDICA (UNII: 23Z87HTQ6P) | | |
| PHENO XYETHANO L (UNII: HIE49 2ZZ3T) | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | |

| Packaging | | | |
|--------------------|---------------------|----------------------|--------------------|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:64990-605-05 | 60 mL in 1 BOTTLE | | |
| | | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part333D | 12/28/2009 | |
| | | | |

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