After 10 minutes, rinse off with water.

6 ADVERSE REACTIONS

4 CONTRAINDICATIONS

3 DOSAGE FORMS AND STRENGTHS

1.1 Indication

1 INDICATIONS AND USAGE

FULL PRESCRIBING INFORMATION: CONTENTS*

Lotion: 0.5% (3)

SKLICE Lotion is a pediculicide indicated for the topical treatment of head lice infestations in patients 6 months of age and older. SKLICE Lotion is an off-white to tan lotion containing ivermectin. SKLICE Lotion should be used in the context of an overall lice management program:

• Wash (in hot water) or dry-clean all recently worn clothing, hats, used bedding and towels.

• Wash (in hot water) or dry-clean all recently used梳es, brushes and hair conditioners.

• Apply SKLICE Lotion to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair of the entire scalp.

• Allow SKLICE Lotion to remain in place for 10 minutes.

• Wash (in hot water) or dry-clean all recently worn clothing, hats, used bedding and towels.

• Discard any unused portion.

• Do not use more than once every 24 hours.

See 17 for the PATIENT COUNSELING and FDA-approved patient labeling.

Safety and effectiveness in pediatric patients below the age of 6 months have not been established.

See 17 for the PATIENT COUNSELING and FDA-approved patient labeling.

6 months. SKLICE Lotion is not recommended in pediatric patients under 6 months of age because the effects of ivermectin on the breastfed infant from SKLICE Lotion application of SKLICE to lactating women has not been studied.

8.4 Pediatric Use

Systemic embryofetal development studies were conducted in mice, rats, and rabbits. Adverse reactions reported in humans, either by ingestion, inhalation, injection, or exposure to body surfaces, the effects of ivermectin in human newborns, the effects of ivermectin in infants, rash, frames, headache, nausea, xerostomia, and diarrhea. Other adverse effects that have been reported include: lacrimation, ataxia, diplopia, tinnitus, and dysphonia. Other adverse effects that have been reported: lacrimation, ataxia, diplopia, tinnitus, and dysphonia. Other adverse effects that have been reported: lacrimation, ataxia, diplopia, tinnitus, and dysphonia. Other adverse effects that have been reported: lacrimation, ataxia, diplopia, tinnitus, and dysphonia. Other adverse effects that have been reported: lacrimation, ataxia, diplopia, tinnitus, and dysphonia. Other adverse effects that have been reported: lacrimation, ataxia, diplopia, tinnitus, and dysphonia.
SKLICE® (sklice) Lotion, 0.5% is supplied in a 4 oz (117g) laminate tube (NDC 24338-183-04).

11.3 NONCLINICAL TOXICOLOGY

Ivermectin had no adverse effects on fertility in rats at repeated oral doses of up to 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Ivermectin was not genotoxic in vitro in the Ames test, the mouse lymphoma assay, or the unscheduled DNA synthesis assay in human fibroblasts.

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of Ivermectin.

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

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Long-term studies in animals have not been performed to evaluate the carcinogenic potential of Ivermectin.

General information about the safe and effective use of SKLICE Lotion.

1.1 what to avoid

Do not use SKLICE Lotion to treat any skin conditions or sensitivities without talking to your healthcare provider first.

When you complete your treatment with SKLICE Lotion, do not wash your hair or scalp with shampoo for at least 24 hours after application.

How should I store SKLICE Lotion?

Store at room temperature between 68°F to 77°F (20°C to 25°C).

Do not freeze SKLICE Lotion.

Use up to 1 entire tube (4 oz) to completely cover scalp and hair.

Always wash hands after applying SKLICE Lotion.

Use the top of cap to break the tamper seal on the tube (see Figure A).

Instructions for Use

Use SKLICE Lotion exactly as prescribed. Your healthcare provider will prescribe the treatment that is right for you.

Use SKLICE Lotion when your hair is dry.

It is important to use enough SKLICE Lotion to completely coat all of your hair and scalp.

Leakage of SKLICE Lotion on your hair and scalp for a full 10 minutes, and then rinse off with water.

You need to completely cover all of your hair and scalp.

SKLICE Lotion that is written for health professionals.

General information about the safe and effective use of SKLICE Lotion.

This Patient Information and Instructions for Use have been approved by the U.S. Food and Drug Administration.

Revised: 06/2017

SCL-PL-104

It is important to completely cover your entire head so that all lice and eggs are exposed to the lotion. Use that hair coat from the scalp to your shoulders.

Leakage of SKLICE Lotion on your hair and scalp for a full 10 minutes, and then rinse off with water.

You can also ask your healthcare provider or pharmacist for information about SKLICE Lotion that is written for health professionals.

To help prevent the spread of lice from one person to another, here are some steps you can take:

Do not share combs, brushes, hats, scarves, bandannas, ribbons, barrettes, hair bands, towels, helmets, or other hair-related personal items with anyone else, whether they have lice or not.

Before finishing treatment with lice treatment, check everyone in your family for lice.

Do not wash your hair or scalp with shampoo for at least 24 hours after application.

Machine wash any bedding and clothing used by anyone having lice. Machine wash at 68°F to 77°F (20°C to 25°C).

You may need to use up to 1 entire tube (4 oz) to completely cover scalp and hair.

If you have any skin conditions or sensitivities, have any skin problems.

Inform the patient and caregiver of the following instructions:

Please do not use SKLICE Lotion on the face.

Use the top of cap to break the tamper seal on the tube (see Figure A).

Instructions for Use

Use SKLICE Lotion exactly as prescribed. Your healthcare provider will prescribe the treatment that is right for you.

Use SKLICE Lotion when your hair is dry.

It is important to use enough SKLICE Lotion to completely coat all of your hair and scalp.

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You can also ask your healthcare provider or pharmacist for information about SKLICE Lotion that is written for health professionals.

To help prevent the spread of lice from one person to another, here are some steps you can take:

Do not share combs, brushes, hats, scarves, handkerchiefs, barrettes, hair bands, towels, helmets, or other hair-related personal items with anyone else, whether they have lice or not.

Before finishing treatment with lice treatment, check everyone in your family for lice.

Do not wash your hair or scalp with shampoo for at least 24 hours after application.

Machine wash any bedding and clothing used by anyone having lice. Machine wash at 68°F to 77°F (20°C to 25°C).