

**Sklice**  
(ivermectin)  
Lotion, 0.5%

**#1 PRESCRIBED BRAND FOR HEAD LICE<sup>1</sup>**



**DON'T BUG OUT  
SKLICE LOTION  
KILLS LICE**



Sklice Lotion is a prescription medicine for topical use on the hair and scalp only, for treatment of head lice in people 6 months of age and older.

Sklice Lotion should be used in the context of an overall lice management program.

## **IMPORTANT SAFETY INFORMATION FOR SKLICE LOTION**

The most common side effects from Sklice Lotion include eye redness or soreness, eye irritation, dandruff, dry skin, and burning sensation of the skin.

Please see additional Important Safety Information and full Prescribing Information on the following pages.

For more information, please visit **[www.Skllice.com](http://www.Skllice.com)**.

**arbor**  
PHARMACEUTICALS, LLC

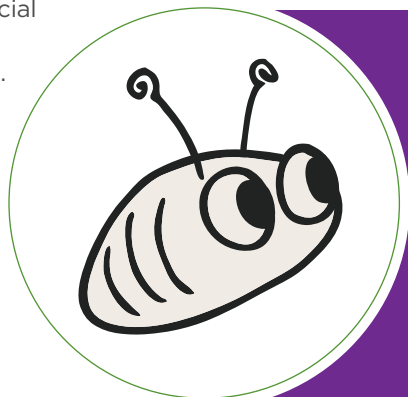
# IF YOU THINK YOUR CHILD HAS HEAD LICE, ASK YOUR DOCTOR ABOUT PRESCRIPTION SKLICE LOTION TODAY.

Head lice are unwelcome visitors with the potential to turn your whole household upside down. Talk with your health care provider about how prescription Sklice Lotion treats head lice in just 10 minutes, with no nit combing required!<sup>2</sup> Sklice Lotion is FDA approved as a 10-minute treatment for head lice that can be used on people 6 months of age and older.<sup>2,3</sup> But treatment is just one step in getting rid of head lice. See below to read more about Sklice Lotion and find useful tips that can help you stop the spread of lice.

Sklice Lotion should be used in the context of an overall lice management program:

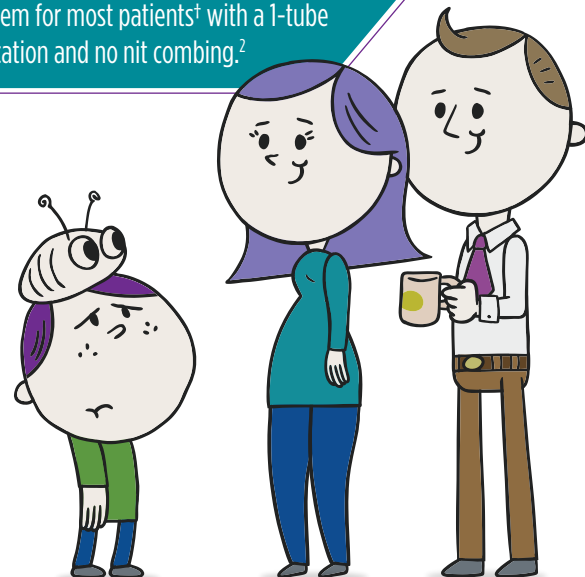
- Ask your child not to share combs, brushes, hats, scarves, bandanas, hair bands, ribbons, barrettes, or towels—basically, anything that is worn or used on the head<sup>4</sup>
- If there's a head lice infestation at your child's school, it's recommended to put sleepovers on hold for a while. This will help to avoid head-to-head contact with other children who may have lice<sup>4</sup>

A fine-tooth comb or special nit comb may be used to remove dead lice and nits.



## SKLICE LOTION KILLS LICE

In 2 clinical studies,\* Sklice Lotion resolved the head lice problem for most patients<sup>†</sup> with a 1-tube application and no nit combing.<sup>2</sup>



\*Two randomized, double-blind, vehicle-controlled trials in participants 6 months of age and older with head lice infestations. The primary efficacy was assessed as the proportion of participants who were free of live lice at day 2 and through day 8 to the final evaluation 14 (+2) days following a single application.

<sup>†</sup>Fourteen days after treatment, no live lice were observed in 76.1% (54/71) and 71.4% (50/70) of participants.

## IMPORTANT SAFETY INFORMATION FOR SKLICE LOTION

The most common side effects from Sklice Lotion include eye redness or soreness, eye irritation, dandruff, dry skin, and burning sensation of the skin.

To prevent accidental ingestion, adult supervision is required for pediatric application. Avoid contact with eyes.

Please see additional Important Safety Information and full Prescribing Information on the following pages.

## HOW TO APPLY SKLICE LOTION

Be sure to ask your doctor, nurse, or pharmacist if you have any questions about the right way to apply Sklice Lotion.

### FOLLOW THE STEPS<sup>2</sup>



#### STEP 1

Hair and scalp must be dry before applying Sklice Lotion. Use the top of the cap to break the tamper-evident seal on the tube.



#### STEP 2

Completely cover scalp and hair closest to the scalp first, apply outward toward the ends of hair, and rub Sklice Lotion throughout hair. Be sure that each hair is covered from the scalp to the tip, so that all lice and eggs are exposed to lotion. Use up to one entire tube completely. Allow product to stay on hair and scalp for 10 minutes.



#### STEP 3

After 10 minutes, completely rinse Sklice Lotion from hair and scalp using only water. You or anyone who helps you apply Sklice Lotion should wash their hands after application. Do not use Sklice Lotion again without talking to your health care provider first.

- For topical use only. Do not swallow. Sklice Lotion is not for oral, ophthalmic, or intravaginal use<sup>2</sup>
- The tube is intended for single use; discard any unused portion<sup>2</sup>
- Sklice Lotion should be used in the context of an overall lice management program<sup>2</sup>

## 5 STEPS FOR MANAGING HEAD LICE IN YOUR HOUSE

Like any parent dealing with head lice for the first time, you may have a few questions. This checklist will help you get started.

#### STEP 1

Check all family members for lice and nits. Consider calling your doctor right away to set up an appointment and get treatment advice and guidance. If you suspect any family members have lice, it's a good idea to take them to the doctor as well.

#### STEP 2

See your doctor. Ask about treatment options. Pick up the prescription from the pharmacy. Make sure you understand exactly how to use the medication before leaving the pharmacy.

#### STEP 3

Remove lice from your house. Identify items that might contain head lice, such as pillows/bed linens, stuffed animals, hats, scarves, helmets, clothes. Machine-wash all washable items in hot water (130°F).<sup>4,6</sup> Seal items that can't be washed in plastic bags for 2 weeks.<sup>4</sup>

#### STEP 4

Share the info. Call parents of children who may have been in close contact with yours.<sup>4</sup> Cancel all sleepovers and play dates until you're sure your child is lice free.<sup>2</sup> Notify your child's school.<sup>4</sup>

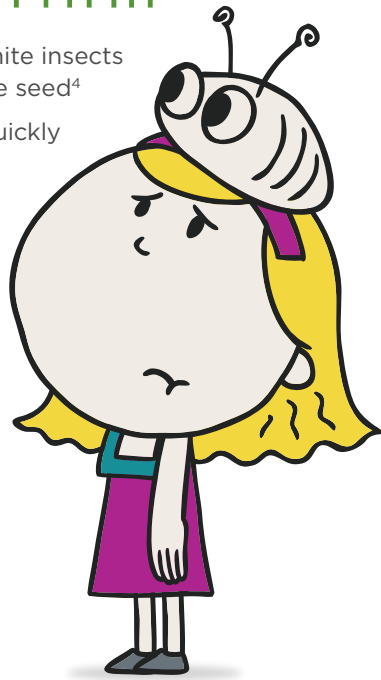
#### STEP 5

Don't bug out. Take a deep breath. Reassure your child that it's OK. Help your child understand that it's not their fault. Anyone can get lice, no matter how clean their hair or house is or where they live, go to school, or play.

Please see Important Safety Information and full Prescribing Information on the following pages.

## FOCUS ON FACTS, NOT MYTH

- Head lice are 6-legged, grayish-white insects that are about the size of a sesame seed<sup>4</sup>
- They do not jump or fly; they crawl quickly from person to person through head-to-head contact<sup>4</sup>
- Lice don't live very long off the head because they need blood to survive<sup>4</sup>
- It takes about 8 or 9 days for head lice eggs (nits) to hatch<sup>4</sup>
- The most common head lice symptom is an itchy scalp, but only people who are allergic to head lice saliva experience this<sup>4</sup>
- There's no scientific evidence that home remedies work<sup>5</sup>



**HEAD LICE DO NOT INFEST PETS,  
AND PETS DO NOT SPREAD HEAD LICE.<sup>4</sup>**

**References:** 1. Data on file. Arbor Pharmaceuticals, LLC. 2. Sklice Lotion [package insert]. 3. US Food and Drug Administration. Sklice Lotion FDA approval letter. [http://www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2012/202736s000ltr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/202736s000ltr.pdf). Accessed August 2, 2016. 4. Centers for Disease Control and Prevention. Frequently asked questions (FAQs). [http://cdc.gov/parasites/lice/head/gen\\_info/faqs.html](http://cdc.gov/parasites/lice/head/gen_info/faqs.html). Accessed August 2, 2016. 5. Centers for Disease Control and Prevention. Treatment frequently asked questions. [http://www.cdc.gov/parasites/lice/head/gen\\_info/faqs\\_treat.html](http://www.cdc.gov/parasites/lice/head/gen_info/faqs_treat.html). Accessed August 2, 2016. 6. Centers for Disease Control and Prevention. Prevention & control. <http://www.cdc.gov/parasites/lice/head/prevent.html>. Accessed August 2, 2016.

## IMPORTANT SAFETY INFORMATION FOR SKLICE LOTION

### INDICATION:

Sklice Lotion is a prescription medicine for topical use on the hair and scalp only, for treatment of head lice in people 6 months of age and older.

### ADJUNCTIVE MEASURES

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 personal care items such as combs, brushes, and hair clips in hot water.

A fine-tooth comb or special nit comb may be used to remove dead lice and nits.

### BEFORE USING SKLICE LOTION, TELL YOUR DOCTOR IF YOU OR YOUR CHILD:

- have any skin conditions or sensitivities
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if Sklice Lotion can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Sklice Lotion passes into your breast milk.

### IMPORTANT SAFETY INFORMATION FOR SKLICE LOTION:

To prevent accidental ingestion, adult supervision is required for pediatric application. Avoid contact with eyes.

The most common side effects from Sklice Lotion include eye redness or soreness, eye irritation, dandruff, dry skin, and burning sensation of the skin.

Talk with your doctor if you or your child have any side effect that bothers you or that does not go away. You may report side effects to the FDA at 1-800-FDA-1088.

**For more information, please see full Prescribing Information for Sklice Lotion on the following pages.**

# YOU MAY PAY NO MORE THAN \$30\* FOR SKLICE LOTION

## HERE'S HOW TO REDEEM YOUR SKLICE SAVINGS COUPON!

1. Get a prescription for Sklice Lotion from your doctor
2. Ask your doctor for a Sklice Lotion savings coupon, or download and print the coupon online at [www.Skllice.com](http://www.Skllice.com)
3. Hand the prescription and your Sklice Lotion savings coupon to your pharmacist

\*Must meet eligibility requirements. Arbor Pharmaceuticals reserves the right to rescind, revoke, or amend this offer without notice. Expiration date: 12/31/2018.

SEE **WWW.SKLLICE.COM** OR  
BACK SIDE OF SAVINGS CARD  
FOR TERMS AND CONDITIONS.



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use SKLICE® Lotion safely and effectively. See full prescribing information for SKLICE Lotion.

SKLICE (ivermectin) Lotion, 0.5%, for topical use  
Initial U.S. Approval: 1996

INDICATIONS AND USAGE

SKLICE Lotion is a pediculicide indicated for the topical treatment of head lice infestations in patients 6 months of age and older. (1)

DOSAGE AND ADMINISTRATION

- For topical use only. Not for oral, ophthalmic or intravaginal use. (2)
- Apply SKLICE Lotion to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp. (2)
- After 10 minutes, rinse off with water. (2)
- For single use. Discard any unused portion. (2)

DOSAGE FORMS AND STRENGTHS

Lotion: 0.5% (3)

FULL PRESCRIBING INFORMATION: CONTENTS\*

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FULL PRESCRIBING INFORMATION

1INDICATIONS AND USAGE

1.1Indication

SKLICE® Lotion is indicated for the topical treatment of head lice infestations in patients 6 months of age and older.

1.2Adjunctive Measures

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 personal care items such as combs, brushes and hair clips in hot water.
- A fine-tooth comb or special nit comb may be used to remove dead lice and nits.

2DOSAGE AND ADMINISTRATION

For topical use only. SKLICE Lotion is not for oral, ophthalmic, or intravaginal use.

Apply SKLICE Lotion to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp. Leave SKLICE Lotion on the hair and scalp for 10 minutes, and then rinse off with water.

The tube is intended for single use; discard any unused portion.

Avoid contact with eyes.

3DOSAGE FORMS AND STRENGTHS

Lotion: 0.5%; each gram of lotion contains 5 mg of ivermectin. SKLICE Lotion is an off-white to tan lotion.

4CONTRAINDICATIONS

None.

CONTRAINDICATIONS

None. (4)

WARNINGS AND PRECAUTIONS

Accidental ingestion in pediatric patients may occur: Administer only under direct adult supervision. (5.1)

ADVERSE REACTIONS

Most common adverse reactions (incidence <1%) are conjunctivitis, ocular hyperemia, eye irritation, dandruff, dry skin, and skin burning sensation. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Arbor Pharmaceuticals, LLC at 1-866-516-4950 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

USE IN SPECIFIC POPULATIONS

Safety and effectiveness in pediatric patients below the age of 6 months have not been established. (8.4)

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

10OVERDOSAGE

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\*Sections or subsections omitted from the full prescribing information are not listed.

5WARNINGS AND PRECAUTIONS

5.1Ingestion in Pediatric Patients

In order to prevent ingestion, SKLICE Lotion should only be administered to pediatric patients under the direct supervision of an adult.

6ADVERSE REACTIONS

6.1Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The data described below reflect exposure to a single 10 minute treatment of SKLICE Lotion in 379 patients, ages 6 months and older, in placebo-controlled trials. Of these subjects, 47 subjects were age 6 months to 4 years, 179 subjects were age 4 to 12 years, 56 subjects were age 12 to 16 years and 97 subjects were age 16 or older. Adverse reactions, reported in less than 1% of subjects treated with SKLICE Lotion, include conjunctivitis, ocular hyperemia, eye irritation, dandruff, dry skin, and skin burning sensation.

8USE IN SPECIFIC POPULATIONS

8.1Pregnancy

Pregnancy Category C

There are no adequate and well-controlled studies with SKLICE Lotion in pregnant women. SKLICE Lotion should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

No comparisons of animal exposure with human exposure are provided due to the low systemic exposure noted in the clinical pharmacokinetic study *[see Clinical Pharmacology (12.3)]*.

Human Data

There are published reports of oral ivermectin use during human pregnancy. In an open label study, 397 women in their second trimester of pregnancy were treated with ivermectin tablets and albendazole at the labeled dose rate for soil-transmitted helminths and compared with a pregnant, non-treated population. No differences in pregnancy outcomes were observed between treated and untreated populations.

Animal Data

Systemic embryofetal development studies were conducted in mice, rats and rabbits. Oral doses of 0.1, 0.2, 0.4, 0.8, and 1.6 mg/kg/day ivermectin were administered during the period of organogenesis (gestational days 6–15) to pregnant female mice. Maternal death occurred at 0.4 mg/kg/day and above. Cleft palate occurred in the fetuses from the 0.4, 0.8, and 1.6 mg/kg/day groups. Exencephaly was seen in the fetuses from the 0.8 mg/kg group. Oral doses of 2.5, 5, and 10 mg/kg/day ivermectin were administered during the period of organogenesis (gestational days 6–17) to pregnant female rats. Maternal death and pre-implantation loss occurred at 10 mg/kg/day. Cleft palate and wavy ribs were seen in fetuses from the 10 mg/kg/day group. Oral doses of 1.5, 3, and 6 mg/kg/day ivermectin were administered during the period of organogenesis (gestational days 6–18) to pregnant female rabbits. Maternal toxicity and abortion occurred at 6 mg/kg/day. Cleft palate and clubbed forepaws occurred in the fetuses from the 3 and 6 mg/kg groups. These teratogenic effects were found only at or near doses that were maternally toxic to the pregnant female. Therefore, ivermectin does not appear to be selectively fetotoxic to the developing fetus.

8.3Nursing Mothers

Following oral administration, ivermectin is excreted in human milk in low concentrations. This has not been evaluated following topical administration. Caution should be exercised when SKLICE Lotion is administered to a nursing woman.

8.4Pediatric Use

The safety and effectiveness of SKLICE Lotion have been established for pediatric patients 6 months of age and older *[see Clinical Pharmacology (12.3) and Clinical Studies (14)]*.

The safety of SKLICE Lotion has not been established in pediatric patients below the age of 6 months. SKLICE Lotion is not recommended in pediatric patients under 6 months of age because of the potential increased systemic absorption due to a high ratio of skin surface area to body mass and the potential for an immature skin barrier and risk of ivermectin toxicity.

8.5Geriatric Use

Clinical studies of SKLICE Lotion did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

10OVERDOSAGE

In accidental or significant exposure to unknown quantities of veterinary formulations of ivermectin in humans, either by ingestion, inhalation, injection, or exposure to body surfaces, the following adverse effects have been reported most frequently: rash, edema, headache, dizziness, asthenia, nausea, vomiting, and diarrhea. Other adverse effects that have been reported include: seizure, ataxia, dyspnea, abdominal pain, paresthesia, urticaria, and contact dermatitis.

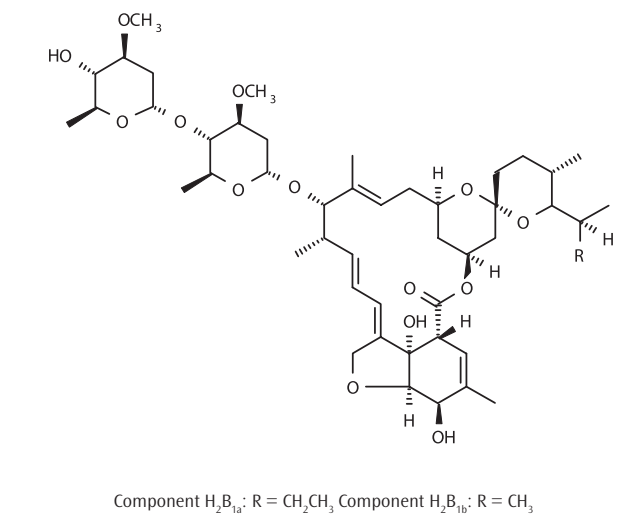
In case of accidental poisoning, supportive therapy, if indicated, should include parenteral fluids and electrolytes, respiratory support (oxygen and mechanical ventilation if necessary) and pressor agents if clinically significant hypotension is present. Induction of emesis and/or gastric lavage as soon as possible, followed by purgatives and other routine anti-poison measures, may be indicated if needed to prevent absorption of ingested material.

11DESCRIPTION

SKLICE (ivermectin) Lotion, for topical administration, is an off-white/tan lotion containing 0.5% ivermectin.

Ivermectin, the active ingredient, is a pediculicide, derived from the fermentation of a soil dwelling actinomycete, *Streptomyces avermitilis*.

Ivermectin is a mixture containing at least 90% 5-O-demethyl-22,23-dihydroavermectin A<sub>1a</sub> and less than 10% 5-O-demethyl-25-de(1-methylpropyl)-22,23-dihydro25-(1-methylethyl) avermectin A<sub>1a</sub>, generally referred to as 22,23-dihydroavermectin B<sub>1a</sub> and B<sub>1b</sub>, or H<sub>2</sub>B<sub>1a</sub> and H<sub>2</sub>B<sub>1b</sub>, respectively. The respective empirical formulas are C<sub>48</sub>H<sub>74</sub>O<sub>14</sub> and C<sub>47</sub>H<sub>72</sub>O<sub>14</sub>, with molecular weights of 875.10 and 861.07, respectively. The structural formulas are:



SKLICE Lotion contains the following inactive ingredients: water, olive oil, oleyl alcohol, Crodalan AWS, lanolin alcohol, cyclomethicone, shea butter, sodium citrate, sorbitan tristearate, methylparaben, propylparaben, and citric acid.

12CLINICAL PHARMACOLOGY

12.1Mechanism of Action

Ivermectin, a member of the avermectin class, causes death of parasites, primarily through binding selectively and with high affinity to glutamate-gated chloride channels, which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA). The selective activity of compounds of this class is attributable to the fact that some mammals do not have glutamate-gated chloride channels, the avermectins have a low affinity for mammalian ligand-gated chloride channels, and ivermectin does not readily cross the blood-brain barrier in humans.

12.2Pharmacodynamics

The pharmacodynamics of SKLICE Lotion are unknown.

12.3Pharmacokinetics

The absorption of ivermectin from SKLICE Lotion was evaluated in a clinical study in subjects aged from 6 months to 3 years. This study evaluated pharmacokinetics in 20 lice infested subjects, and 13 of these subjects weighed 15 kg or less (overall weight range 8.5-23.9 kg). All enrolled subjects received a single treatment with SKLICE Lotion. The systemic ivermectin exposure was evaluated using an assay with a lower limit of quantitation of 0.05 ng/mL. The mean (± standard deviation) plasma maximum concentration (C<sub>max</sub>) and area under the concentration-time curve from 0 to time of last measurable concentration (AUC<sub>0-last</sub>) were 0.24 ± 0.23 ng/mL and 6.7 ± 11.2hr•ng/mL, respectively. These levels are much lower than those observed following oral administration of 165 mcg/kg dose of ivermectin.



13 NONCLINICAL TOXICOLOGY

**13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**  
Long-term studies in animals have not been performed to evaluate the carcinogenic potential of SKLICE Lotion or ivermectin.

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

Ivermectin had no adverse effects on fertility in rats at repeated oral doses of up to 3.6 mg/kg/day.

14 CLINICAL STUDIES

Two identical multi-center, randomized, double-blind, vehicle-controlled studies were conducted in subjects 6 months of age and older with head lice infestation. All subjects received a single application of either SKLICE Lotion or vehicle control with instructions not to use a nit comb. For the evaluation of efficacy, the youngest subject from each household was considered to be the index subject of the household (N=289). Other enrolled infested household members received the same treatment as the youngest subject and were evaluated for all safety parameters [see *Adverse Reactions* (6.1)].

The primary efficacy was assessed as the proportion of index subjects who were free of live lice at day 2 and through day 8 to the final evaluation 14 (+2) days following a single application. Subjects with live lice present at any time up to the final evaluation were considered treatment failures. Table 1 contains the proportion of subjects who were free of live lice in each of the two trials.

**Table 1: Proportion of Subjects Free of Live Lice 14 Days After Treatment**

Study	Vehicle % (n/N)	SKLICE Lotion % (n/N)
Study 1	16.2% (12/74)	76.1% (54/71)
Study 2	18.9% (14/74)	71.4% (50/70)

16 HOW SUPPLIED/STORAGE AND HANDLING

SKLICE Lotion, 0.5% is supplied in a 4 oz (117g) laminate tube (NDC 24338-183-04).

Store at room temperature 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP controlled room temperature]. Do not freeze.

17 PATIENT COUNSELING INFORMATION

"See FDA-approved patient labeling (Patient Information)".  
Inform the patient and caregiver of the following instructions:

- Apply SKLICE Lotion to dry scalp and dry scalp hair.
- Avoid contact with eyes.
- Do not swallow SKLICE Lotion.
- Keep out of reach of children. Use on children should be under the direct supervision of an adult.
- For single use only; do not retreat.
- Discard tube after use.
- Wash hands after applying SKLICE Lotion.

Patient Information

**SKLICE® (sklice) (ivermectin) Lotion, 0.5%**

**Important: For use on scalp hair and scalp only. Do not use SKLICE Lotion in your eyes, mouth or vagina.**

Read the Patient Information that comes with SKLICE Lotion. This leaflet does not take the place of talking to your healthcare provider about your medical condition or treatment.

**What is SKLICE Lotion?**

SKLICE Lotion is a prescription medicine for topical use on the hair and scalp only. SKLICE Lotion is used to treat head lice in people 6 months of age and older.

It is not known if SKLICE Lotion is safe and effective for children under 6 months of age.

**What should I tell my healthcare provider before using SKLICE Lotion?**

Before using SKLICE Lotion, tell your healthcare provider if you or your child:

- have any skin conditions or sensitivities,
- have any other medical conditions,
- are pregnant or plan to become pregnant. It is not known if SKLICE Lotion can harm your unborn baby, and
- are breastfeeding or plan to breastfeed. It is not known if SKLICE Lotion passes into your breast milk. Talk to your healthcare provider if you are breastfeeding.

**How should I use SKLICE Lotion?**

- Use SKLICE Lotion exactly as prescribed. Your healthcare provider will prescribe the treatment that is right for you. Do not change your treatment unless you talk to your healthcare provider.
- 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. Leave SKLICE Lotion on your hair and scalp for a full 10 minutes. **See the detailed “Patient Instructions for Use” at the end of this leaflet.**
- You need to completely cover all the scalp and hair with lotion. Make sure that you and anyone who helps you apply SKLICE Lotion reads and understands this leaflet and the Patient Instructions for Use.
- Children will need an adult to apply SKLICE Lotion for them.
- Do not swallow SKLICE Lotion. If swallowed, call your healthcare provider or go to the nearest emergency room right away.
- Do not get SKLICE Lotion into your eyes. If SKLICE Lotion gets in your eye, gently flush with water.
- Wash your hands after applying SKLICE Lotion.

When you complete your dose of SKLICE Lotion, do not use SKLICE Lotion again without talking to your healthcare provider first.

**What are the possible side effects of SKLICE Lotion?**

**The most common side effects of SKLICE Lotion include:**

- eye redness or soreness
- eye irritation
- dandruff
- dry skin
- burning sensation of the skin

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of SKLICE Lotion. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

**How should I store SKLICE Lotion?**

- Store SKLICE Lotion at room temperature between 68° to 77°F (20° to 25°C).
- Do not freeze SKLICE Lotion.
- Safely throw away any unused SKLICE Lotion.

**Keep SKLICE Lotion and all medicines out of reach of children.**

**What are the ingredients in SKLICE Lotion?**

Active ingredient: ivermectin

Inactive ingredients: water, olive oil, oleyl alcohol, Crodalan AWS, lanolin alcohol, cyclomethicone, shea butter, sodium citrate, sorbitan tristearate, methylparaben, propylparaben, and citric acid

**General information about SKLICE Lotion**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use SKLICE Lotion for a condition for which it was not prescribed. Do not give SKLICE Lotion to other people, even if they have the same symptoms you have. It may harm them. This Patient Information leaflet summarizes the most important information about SKLICE Lotion. If you would like more information, talk to your healthcare provider. You can also ask your healthcare provider or pharmacist for information about SKLICE Lotion that is written for health professionals.

**Patient Instructions for Use**

Before you use SKLICE Lotion, it is important that you read the Patient Information and these Patient Instructions for Use. Be sure that you read, understand, and follow these Patient Instructions for Use so that you use SKLICE Lotion the right way. Ask your healthcare provider or pharmacist if you have questions about the right way to use SKLICE Lotion.

- Your hair and scalp must be dry before applying SKLICE Lotion.
- Use the top of cap to break the tamper seal on the tube (see Figure A).
- Apply SKLICE Lotion directly to **dry hair and scalp** (see Figure B).

**Figure A**



**Figure B**



- Completely cover your scalp and hair closest to the scalp first, and then apply outwards towards the ends of your hair (see Figure C).
- Rub SKLICE Lotion throughout your hair (see Figure D).

**Figure C**



**Figure D**



- It is important to completely cover your entire head so that all lice and eggs are exposed to the lotion. Be sure that each hair is coated from the scalp to the tip.

- Use up to 1 entire tube (4 oz) to completely cover hair and scalp.
- Allow SKLICE Lotion to stay on your hair and scalp for 10 minutes after it has been applied. Use a timer or clock. Start timing after you have completely covered your hair and scalp with SKLICE Lotion (see Figure E).
- After 10 minutes, completely rinse SKLICE Lotion from your hair and scalp using only water (see Figure F).

**Figure E**



**Figure F**



- You or anyone who helps you apply SKLICE Lotion should wash their hands after application.
- Do not use SKLICE Lotion again without talking to your healthcare provider first.

**How do I stop the spread of lice?**

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

- Avoid direct head-to-head contact with anyone known to have live, crawling lice.
- 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.
- Avoid sleepovers and slumber parties during lice outbreaks. Lice can live in bedding, pillows, and carpets that have recently been used by someone with lice.
- After finishing treatment with lice medicine, check everyone in your family for lice after one week. Be sure to talk to your healthcare provider about treatments for those who have lice.
- Machine wash any bedding and clothing used by anyone having lice. Machine wash at high temperatures (150°F) and tumble in a hot dryer for 20 minutes.

**This Patient Information has been approved by the U.S. Food and Drug Administration.**

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