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

**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 >5%) are conjunctivitis, ocular hyperemia, eye irritation, dandruff, dry skin, and skin burning sensation. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Arbor Pharmaceulicals, LLC at 1-866-516-4830 or FDA at 1-800-FDA-1088 or see FDA.gov/medwatch.

**USE IN SPECIFIC POPULATIONS**

Safety and effectiveness in pediatric patients below the age of 6 months have not been established. (8.3)

**DOSAGE FORMS AND STRENGTHS**

Lotion: 0.5% (3)
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 8.5). The primary efficacy was assessed as the proportion of index subjects who were free of live lice in each of the two trials. Table 1 contains the proportion of subjects who were free of live lice in each of the two trials.

<table>
<thead>
<tr>
<th>Study</th>
<th>Vehicle % (n/N)</th>
<th>SKLICE® Lotion % (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1</td>
<td>16.2% (127/794)</td>
<td>76.1% (547/721)</td>
</tr>
<tr>
<td>Study 2</td>
<td>18.9% (14/74)</td>
<td>77.4% (54/78)</td>
</tr>
</tbody>
</table>

**Table 1:** Proportion of subjects free of lice Live 14 Days After Treatment

**CLINICAL STUDIES**

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

Ivermectin was not genotoxic

Carcinogenesis, Mutagenesis, Impairment of Fertility

Ivermectin was not genotoxic

**NONCLINICAL TOXICOLOGY**

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use SKLICE® Lotion for a condition in 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 three 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.

**How should I apply 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.

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

- Have any skin conditions or sensitivities, or
- Have any other medical conditions, or
- 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.

Refrain from applying SKLICE® Lotion to your hair and scalp for 6 months after any treatment with a nit comb.

**How should I use SKLICE® Lotion?**

1. Use SKLICE® Lotion exactly as prescribed. Your healthcare provider will prescribe the treatment that is right for your child. Do not change your treatment unless you talk to your healthcare provider.

2. Use SKLICE® Lotion when your hair is dry.

3. 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.

4. 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 Live. Children will need an adult to apply SKLICE® Lotion for them.

5. Do not swallow SKLICE® Lotion. If swallowed, call your healthcare provider or go to the nearest emergency room right away.

6. Do not get SKLICE® Lotion into your eyes. If SKLICE® Lotion gets in your eyes, gently flush with water.

7. 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 major side effects of SKLICE® Lotion include:

- Burning sensation of the skin

Tell your healthcare provider if you 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.

**How should I store SKLICE® Lotion?**

Store SKLICE® Lotion at room temperature between 68°F to 77°F (20°C to 25°C). Do not freeze. 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, sorbital 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 three 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).

**How to use SKLICE® Lotion**

When applying SKLICE® Lotion, apply outwards towards the ends of your hair. Be sure to talk to your healthcare provider about treatments for those who have live 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.

**Distributed by:**

Arbor Pharmaceuticals, LLC
Atlanta, GA 30328

**Manufactured by:**

DPT Laboratories LTD
San Antonio, TX 78215

**Sklice** is a registered trademark of Arbor Pharmaceuticals, LLC ©2016 Arbor Pharmaceuticals, LLC All rights reserved.

U.S. Patent No. 6,103,248 and other patents pending.

**SKL-PI-01**