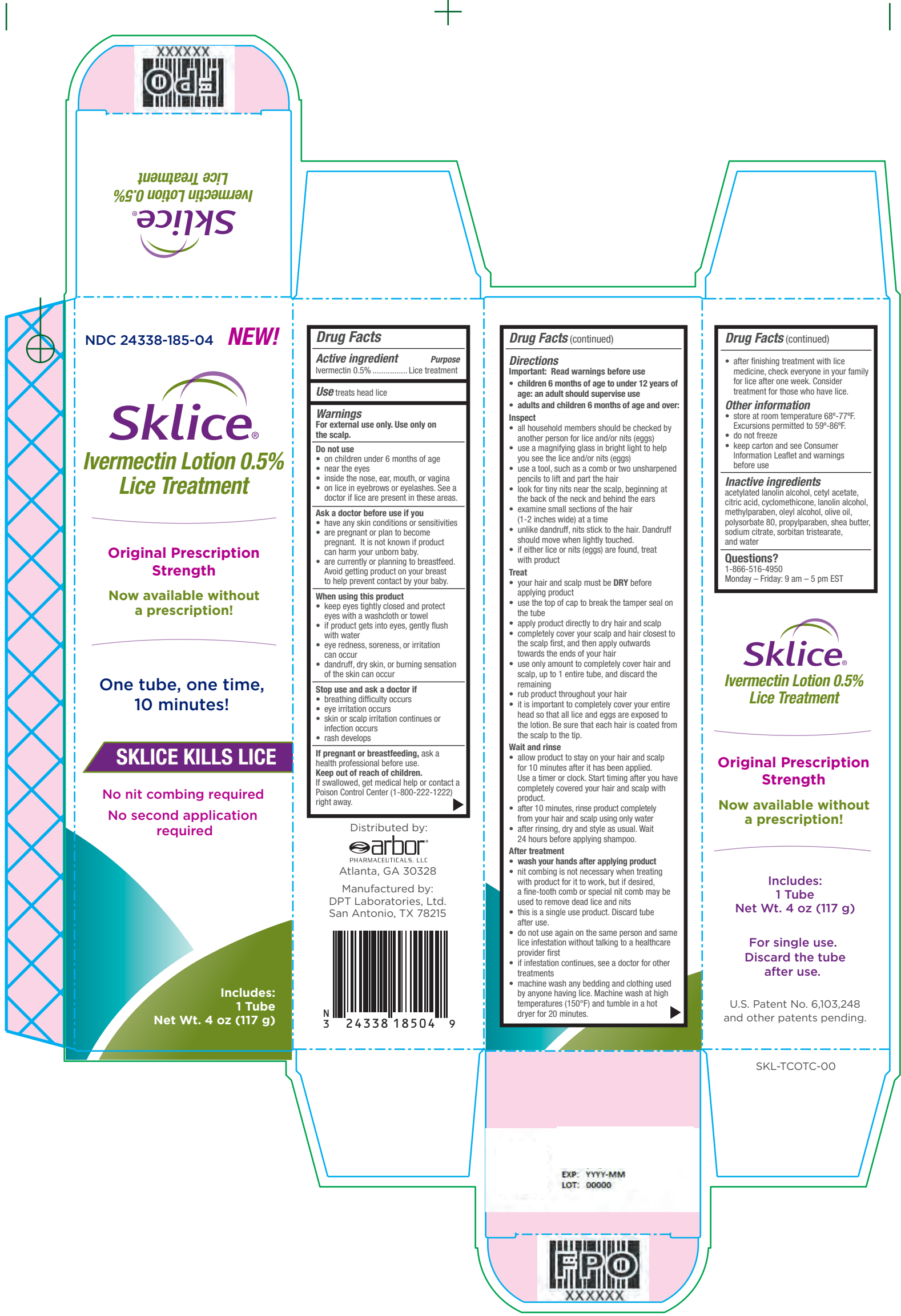


Sklice DPT Outer Carton



Ivermectin Lotion 0.5%
Sklice
Lice Treatment

NDC 24338-185-04 **NEW!**

Sklice
Ivermectin Lotion 0.5%
Lice Treatment

Original Prescription Strength

Now available without a prescription!

One tube, one time, 10 minutes!

SKLICE KILLS LICE

**No nit combing required
No second application required**

Includes:
1 Tube
Net Wt. 4 oz (117 g)

Drug Facts

Active ingredient Purpose
Ivermectin 0.5% Lice treatment

Use treats head lice

Warnings

For external use only. Use only on the scalp.

Do not use

- on children under 6 months of age
- near the eyes
- inside the nose, ear, mouth, or vagina
- on lice in eyebrows or eyelashes. See a doctor if lice are present in these areas.

Ask a doctor before use if you

- have any skin conditions or sensitivities
- are pregnant or plan to become pregnant. It is not known if product can harm your unborn baby.
- are currently or planning to breastfeed. Avoid getting product on your breast to help prevent contact by your baby.

When using this product

- keep eyes tightly closed and protect eyes with a washcloth or towel
- if product gets into eyes, gently flush with water
- eye redness, soreness, or irritation can occur
- dandruff, dry skin, or burning sensation of the skin can occur

Stop use and ask a doctor if

- breathing difficulty occurs
- eye irritation occurs
- skin or scalp irritation continues or infection occurs
- rash develops

If pregnant or breastfeeding, ask a health professional before use.
Keep out of reach of children.
If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Distributed by:
arbor
PHARMACEUTICALS, LLC
Atlanta, GA 30328

Manufactured by:
DPT Laboratories, Ltd.
San Antonio, TX 78215



Drug Facts (continued)

Directions

Important: Read warnings before use

- children 6 months of age to under 12 years of age: an adult should supervise use
- adults and children 6 months of age and over:

Inspect

- all household members should be checked by another person for lice and/or nits (eggs)
- use a magnifying glass in bright light to help you see the lice and/or nits (eggs)
- use a tool, such as a comb or two unsharpened pencils to lift and part the hair
- look for tiny nits near the scalp, beginning at the back of the neck and behind the ears
- examine small sections of the hair (1-2 inches wide) at a time
- unlike dandruff, nits stick to the hair. Dandruff should move when lightly touched.
- if either lice or nits (eggs) are found, treat with product

Treat

- your hair and scalp must be **DRY** before applying product
- use the top of cap to break the tamper seal on the tube
- apply product directly to dry hair and scalp
- completely cover your scalp and hair closest to the scalp first, and then apply outwards towards the ends of your hair
- use only amount to completely cover hair and scalp, up to 1 entire tube, and discard the remaining
- rub product throughout your hair
- 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.

Wait and rinse

- allow product 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 product.
- after 10 minutes, rinse product completely from your hair and scalp using only water
- after rinsing, dry and style as usual. Wait 24 hours before applying shampoo.

After treatment

- **wash your hands after applying product**
- nit combing is not necessary when treating with product for it to work, but if desired, a fine-tooth comb or special nit comb may be used to remove dead lice and nits
- this is a single use product. Discard tube after use.
- do not use again on the same person and same lice infestation without talking to a healthcare provider first
- if infestation continues, see a doctor for other treatments
- 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.

Drug Facts (continued)

- after finishing treatment with lice medicine, check everyone in your family for lice after one week. Consider treatment for those who have lice.

Other information

- store at room temperature 68°-77°F. Excursions permitted to 59°-86°F.
- do not freeze
- keep carton and see Consumer Information Leaflet and warnings before use

Inactive ingredients

acetylated lanolin alcohol, cetyl acetate, citric acid, cyclomethicone, lanolin alcohol, methylparaben, oleyl alcohol, olive oil, polysorbate 80, propylparaben, shea butter, sodium citrate, sorbitan tristearate, and water

Questions?

1-866-516-4950
Monday – Friday: 9 am – 5 pm EST

Sklice
Ivermectin Lotion 0.5%
Lice Treatment

Original Prescription Strength

Now available without a prescription!

Includes:
1 Tube
Net Wt. 4 oz (117 g)

For single use. Discard the tube after use.

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

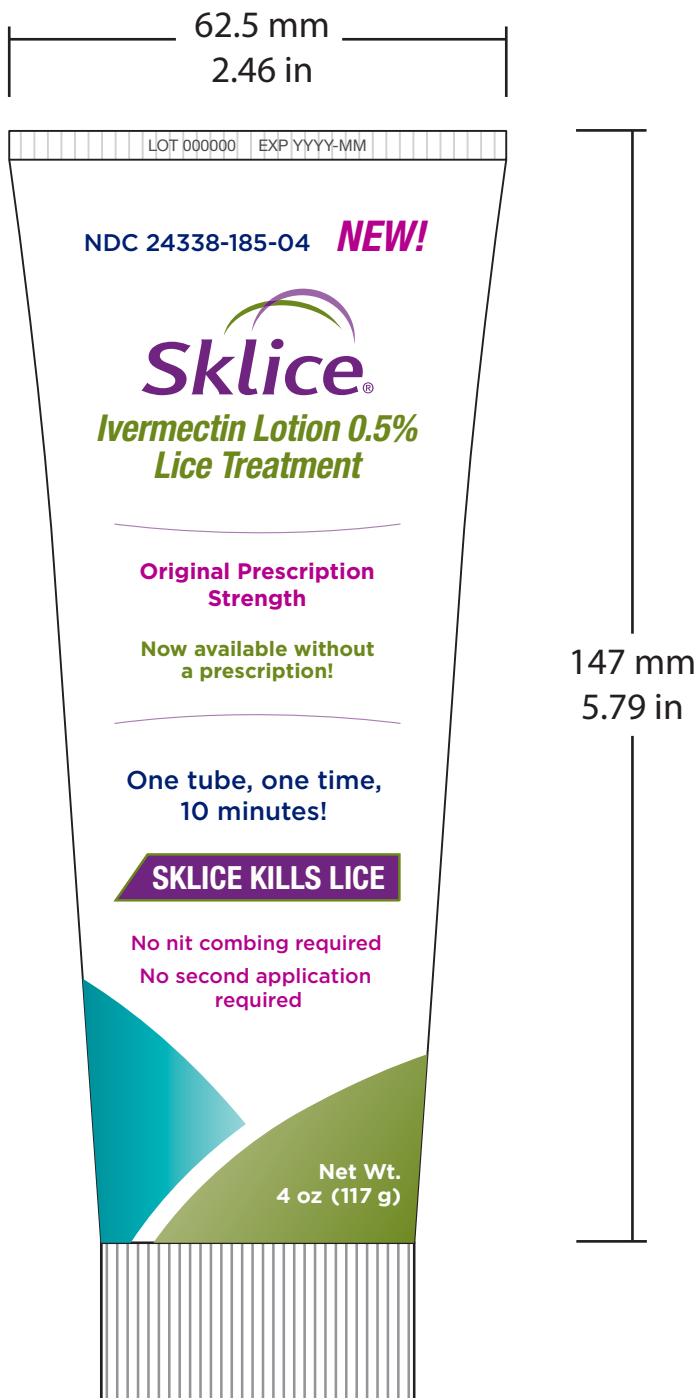
SKL-TCOTC-00

EXP: YYYY-MM
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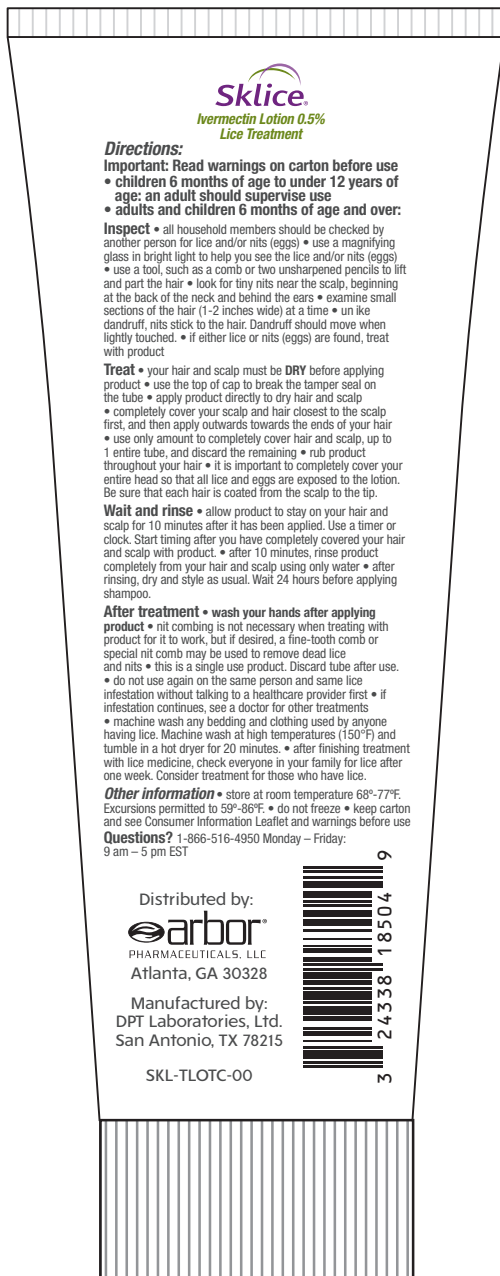
This label may not be the latest approved by FDA.
current labeling information, please visit <https://www.fda.gov/drugsat>

Sklice DPT Tube Front with Primary Display Panel.



Sklice DPT Tube Back

62.5 mm
2.46 in



Sklice.
Ivermectin Lotion 0.5%
Lice Treatment

Directions:

Important: Read warnings on carton before use
• children 6 months of age to under 12 years of age: an adult should supervise use
• adults and children 6 months of age and over:

Inspect • all household members should be checked by another person for lice and/or nits (eggs) • use a magnifying glass in bright light to help you see the lice and/or nits (eggs) • use a tool, such as a comb or two unsharpened pencils to lift and part the hair • look for tiny nits near the scalp, beginning at the back of the neck and behind the ears • examine small sections of the hair (1-2 inches wide) at a time • unike dandruff, nits stick to the hair. Dandruff should move when lightly touched. • if either lice or nits (eggs) are found, treat with product

Treat • your hair and scalp must be DRY before applying product • use the top of cap to break the tamper seal on the tube • apply product directly to dry hair and scalp • completely cover your scalp and hair closest to the scalp first, and then apply outwards towards the ends of your hair • use only amount to completely cover hair and scalp, up to 1 entire tube, and discard the remaining • rub product throughout your hair • 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.

Wait and rinse • allow product 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 product. • after 10 minutes, rinse product completely from your hair and scalp using only water • after rinsing, dry and style as usual. Wait 24 hours before applying shampoo.

After treatment • wash your hands after applying product • nit combing is not necessary when treating with product for it to work, but if desired, a fine-tooth comb or special nit comb may be used to remove dead lice and nits • this is a single use product. Discard tube after use. • do not use again on the same person and same lice infestation without talking to a healthcare provider first • if infestation continues, see a doctor for other treatments • 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. • after finishing treatment with lice medicine, check everyone in your family for lice after one week. Consider treatment for those who have lice.

Other information • store at room temperature 68°-77°F. Excursions permitted to 59°-86°F. • do not freeze • keep carton and see Consumer Information Leaflet and warnings before use

Questions? 1-866-516-4950 Monday – Friday:
9 am – 5 pm EST

Distributed by:

arbor
PHARMACEUTICALS, LLC
Atlanta, GA 30328

Manufactured by:
DPT Laboratories, Ltd.
San Antonio, TX 78215


SKL-TLOT-00



147 mm
5.79 in

Sklice JHS Outer Carton


XXXXXX



UNVARNISH AREA

Sklice
Ivermectin Lotion 0.5%
Lice Treatment

NDC 24338-185-04 **NEW!**



Sklice®
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SKLICE KILLS LICE

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Includes:
1 Tube
Net Wt. 4 oz (117 g)

GLUE FLAP UNVARNISH AREA

Drug Facts	
Active ingredient	Purpose
Ivermectin 0.5%	Lice treatment
Use treats head lice	
Warnings For external use only. Use only on the scalp.	
Do not use	
<ul style="list-style-type: none"> on children under 6 months of age near the eyes inside the nose, ear, mouth, or vagina on lice in eyebrows or eyelashes. See a doctor if lice are present in these areas. 	
Ask a doctor before use if you	
<ul style="list-style-type: none"> have any skin conditions or sensitivities are pregnant or plan to become pregnant. It is not known if product can harm your unborn baby. are currently or planning to breastfeed. Avoid getting product on your breast to help prevent contact by your baby. 	
When using this product	
<ul style="list-style-type: none"> keep eyes tightly closed and protect eyes with a washcloth or towel if product gets into eyes, gently flush with water eye redness, soreness, or irritation can occur dandruff, dry skin, or burning sensation of the skin can occur 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> breathing difficulty occurs eye irritation occurs skin or scalp irritation continues or infection occurs rash develops 	
If pregnant or breastfeeding , ask a health professional before use.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.	
Distributed by: Parbor PHARMACEUTICALS, LLC Atlanta, GA 30328	
Manufactured by: Jubilant HollisterStier General Partnership 16751 Trans-Canada Highway Kirkland, Quebec, Canada H9H 4J4 Made in Canada	
 N 3 24338 18504 9	

Drug Facts (continued)	
Directions	
Important: Read warnings before use	
<ul style="list-style-type: none"> children 6 months of age to under 12 years of age: an adult should supervise use adults and children 6 months of age and over: inspect 	
<ul style="list-style-type: none"> all household members should be checked by another person for lice and/or nits (eggs) use a magnifying glass in bright light to help you see the lice and/or nits (eggs) use a tool, such as a comb or two unsharpened pencils to lift and part the hair look for tiny nits near the scalp, beginning at the back of the neck and behind the ears examine small sections of the hair (1-2 inches wide) at a time unlike dandruff, nits stick to the hair. Dandruff should move when lightly touched. if either lice or nits (eggs) are found, treat with product 	
Treat	
<ul style="list-style-type: none"> your hair and scalp must be DRY before applying product use the top of cap to break the tamper seal on the tube apply product directly to dry hair and scalp completely cover your scalp and hair closest to the scalp first, and then apply outwards towards the ends of your hair use only amount to completely cover hair and scalp, up to 1 entire tube, and discard the remaining rub product throughout your hair 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. 	
Wait and rinse	
<ul style="list-style-type: none"> allow product 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 product. after 10 minutes, rinse product completely from your hair and scalp using only water after rinsing, dry and style as usual. Wait 24 hours before applying shampoo. 	
After treatment	
<ul style="list-style-type: none"> wash your hands after applying product nit combing is not necessary when treating with product for it to work, but if desired, a fine-tooth comb or special nit comb may be used to remove dead lice and nits this is a single use product. Discard tube after use. do not use again on the same person and same lice infestation without talking to a healthcare provider first if infestation continues, see a doctor for other treatments 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. 	

Drug Facts (continued)	
<ul style="list-style-type: none"> after finishing treatment with lice medicine, check everyone in your family for lice after one week. Consider treatment for those who have lice. 	
Other information	
<ul style="list-style-type: none"> store at room temperature 68°-77°F. Excursions permitted to 59°-86°F. do not freeze keep carton and see Consumer Information Leaflet and warnings before use 	
Inactive ingredients	
acetylated lanolin alcohol, cetyl acetate, citric acid, cyclomethicone, lanolin alcohol, methylparaben, oleyl alcohol, olive oil, polysorbate 80, propylparaben, shea butter, sodium citrate, sorbitan tristearate, and water	
Questions?	
1-866-516-4950 Monday – Friday: 9 am – 5 pm EST	

Sklice®
Ivermectin Lotion 0.5%
Lice Treatment

Original Prescription Strength

Now available without a prescription!

Includes:
1 Tube
Net Wt. 4 oz (117 g)


For single use. Discard the tube after use.

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

SKL-TCOTC-J00

EXP: YYYY-MM
LOT: 00000

XXXXXX



This label may not be the latest approved by FDA.
For current labeling information, please visit <https://www.fda.gov/drugsatfd>

Sklice JHS Tube Front with Primary Display Panel.



This label may not be the latest approved by FDA.

For current labeling information, please visit <https://www.fda.gov/drugsatfda>

Sklice JHS Tube Back

62.5 mm

2.46 in

Sklice.

Ivermectin Lotion 0.5%
Lice Treatment

Directions:

Important: Read warnings on carton before use

- children 6 months of age to under 12 years of age: an adult should supervise use
- adults and children 6 months of age and over:

Inspect • all household members should be checked by another person for lice and/or nits (eggs) • use a magnifying glass in bright light to help you see the lice and/or nits (eggs) • use a tool, such as a comb or two unsharpened pencils to lift and part the hair • look for tiny nits near the scalp, beginning at the back of the neck and behind the ears • examine small sections of the hair (1-2 inches wide) at a time • unlike dandruff, nits stick to the hair. Dandruff should move when lightly touched. • if either lice or nits (eggs) are found, treat with product

Treat • your hair and scalp must be DRY before applying product • use the top of cap to break the tamper seal on the tube • apply product directly to dry hair and scalp • completely cover your scalp and hair closest to the scalp first, and then apply outwards towards the ends of your hair • use only amount to completely cover hair and scalp, up to 1 entire tube, and discard the remaining • rub product throughout your hair • 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.

Wait and rinse • allow product 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 product. • after 10 minutes, rinse product completely from your hair and scalp using only water • after rinsing, dry and style as usual. Wait 24 hours before applying shampoo.

After treatment • wash your hands after applying product • nit combing is not necessary when treating with product for it to work, but if desired, a fine-tooth comb or special nit comb may be used to remove dead lice and nits • this is a single use product. Discard tube after use. • do not use again on the same person and same lice infestation without talking to a healthcare provider first • if infestation continues, see a doctor for other treatments • 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. • after finishing treatment with lice medicine, check everyone in your family for lice after one week. Consider treatment for those who have lice.

Other information • store at room temperature 68°-77°F. Excursions permitted to 59°-86°F. • do not freeze • keep carton and see Consumer Information Leaflet and warnings before use

Questions? 1-866-516-4950 Monday – Friday, 9 am – 5 pm EST

Distributed by:

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PHARMACEUTICALS, LLC

Atlanta, GA 30328

Manufactured by:
Jubilant HollisterStier
General Partnership
Kirkland, Quebec,
Canada H9H 4J4
Made in Canada

SKL-TLOT-C-J00



147 mm

5.79 in

Sklice Consumer Insert Leaflet

SKLICE® Lotion IVERMECTIN

Lice Treatment Lotion

THE FACTS OF LICE

Please read all information before using SKLICE Lotion.

If you or a member of your household has head lice, don't panic. Keep calm.

Anyone can get head lice – it has nothing to do with cleanliness or poor hygiene. Head lice are treatable and very rarely cause serious health problems.

What are head lice?

- Head lice are small insects that live and feed on the human scalp.
- They may get as big as sesame seeds and are brown.
- Lice do not fly or jump from one person to another. They can only crawl.

What are nits?

- Nits are lice eggs laid on the hair near the scalp. One louse may lay over 100 nits.
- Nits are oval shaped, tiny and greyish-white.
- They are attached to hair with a waterproof glue-like substance that cannot be washed out or blown away.

How do head lice spread?

- Head lice spread easily from close head-to-head contact with persons who have lice.
- They may also be spread by sharing hats, helmets, scarves, headphones, brushes, combs, bedding and clothing.

How do you know if you have lice?

- Itching is the most common symptom.
- Scratching behind the ears or the back of the neck is a sign that you should check for head lice.
- Scabs or blood spots may be seen.

How do you prevent the spread of lice?

- 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.

How do I use SKLICE Lotion?

Important: Read warnings before use

- Children 6 months of age to under 12 years of age: an adult should supervise use
- Adults and children 6 months of age and over:

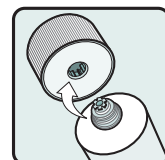
Inspect

- All household members should be checked by another person for lice and/or nits (eggs).
- Use a magnifying glass in bright light to help you see the lice and/or nits (eggs).
- Use a tool, such as a comb or two unsharpened pencils to lift and part the hair.
- Look for tiny nits near the scalp, beginning at the back of the neck and behind the ears.
- Examine small sections of the hair (1-2 inches wide) at a time.
- Unlike dandruff, nits stick to the hair. Dandruff should move when lightly touched.
- If either lice or nits (eggs) are found, treat with product.

Treat

- Your hair and scalp must be **DRY** before applying product.

Figure A



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

- Apply product directly to dry hair and scalp (see **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**).
- Use only amount to completely cover hair and scalp, up to 1 entire tube, and discard the remaining.
- Rub product throughout your hair (see **Figure D**).

Figure B



Figure C

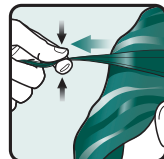


Figure D



- 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.

Wait and rinse

- Allow product 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 product (see **Figure E**).
- After 10 minutes, rinse product completely from your hair and scalp using only water (see **Figure F**).

Figure E



Figure F



- After rinsing, dry and style as usual. Wait 24 hours before applying shampoo.

After treatment

- **Wash your hands after applying product.**
- Nit combing is not necessary when treating with product for it to work, but if desired, a fine-tooth comb or special nit comb may be used to remove dead lice and nits.
- This is a single use product. Discard tube after use.
- Do not use again on the same person and same lice infestation without talking to a healthcare provider first.
- If infestation continues, see a doctor for other treatments.
- 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.
- After finishing treatment with lice medicine, check everyone in your family for lice after one week. Consider treatment for those who have lice.

WARNINGS

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Do not use

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- Near the eyes
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Ask a doctor before use if you

- Have any skin conditions or sensitivities
- Are pregnant or plan to become pregnant. It is not known if product can harm your unborn baby.
- Are currently or planning to breastfeed. Avoid getting product on your breast to help prevent contact by your baby.

When using this product

- Keep eyes tightly closed and protect eyes with a washcloth or towel.
- If product gets into eyes, gently flush with water.
- Eye redness, soreness or irritation can occur.
- Dandruff, dry skin, or burning sensation of the skin can occur.

Stop use and ask a doctor if

- Breathing difficulty occurs
- Eye irritation occurs
- Skin or scalp irritation continues or infection occurs
- Rash develops


If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Questions or comments?

Call 1-866-516-4950
Monday – Friday: 9am – 5 pm EST

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Atlanta, GA 30328
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Rev. XX/20XX
SKL-CIL-00

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/s/

KENDALL A MARCUS
10/27/2020 11:42:00 AM

FRANCIS E BECKER
10/27/2020 11:47:28 AM