

IVERMECTIN- ivermectin lotion
Taro Pharmaceuticals U.S.A., Inc.

Ivermectin

Drug Facts

Active ingredient

Ivermectin 0.5%

Purpose

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.

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 needed 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

- **TAMPER EVIDENT: DO NOT USE IF THE TAMPER SEAL ON THE TUBE HAS BEEN BROKEN.**
- store at room temperature 68°-77°F (20°-25°C)
- do not freeze
- keep carton and see Consumer Information Leaflet and warnings before use

Inactive ingredients

butylated hydroxyanisole, castor oil, cetyl alcohol, citric acid anhydrous, crodalan AWS, cyclomethicone, glycerin, imidurea, lanolin alcohols, methylparaben, oleyl alcohol, olive oil, propylene glycol, propylparaben, purified water, shea butter, sodium citrate anhydrous, sorbitan tristearate and stearyl alcohol.

Questions?

1-866-923-4914

Distributed by:

Taro Pharmaceuticals

U.S.A., Inc.

Hawthorne, NY 10532

Ivermectin Lotion, 0.5%

Lice Treatment Lotion

THE FACTS OF LICE

Please read all information before using Ivermectin 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 or hand-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 Ivermectin 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 needed 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

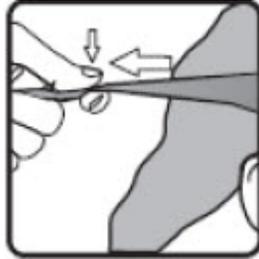


Figure D



- 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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When using this product

- Keep eyes tightly closed and protect eyes with a washcloth or towel.
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- 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
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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 1-866-923-4914

Mfd. by: Taro Pharmaceutical Industries Ltd.

Haifa Bay, Israel 2624761

Made in Israel

Issued: November 2020

PRINCIPAL DISPLAY PANEL - 117 g Tube Carton

Compare to the
active ingredient
in Sklice[®]

NDC 51672-4230-8

Ivermectin
Lotion, 0.5%
Lice Treatment

Original Prescription Strength

Now available without
a prescription!

One tube, one time,
10 minutes!

IVERMECTIN LOTION KILLS LICE

No nit combing required
No second application required

Includes:

1 Tube

Net Wt. 4 oz (117 g)

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862

5215020-0121-0

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Ivermectin 0.5%	Lice treatment

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Ivermectin

Lotion, 0.5%

Lice Treatment

Drug Facts (continued)

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Drug Facts (continued)

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Inactive ingredients

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Questions? 1-866-923-4914

*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Sklice®.



Distributed by:
Taro Pharmaceuticals
U.S.A., Inc.
Hawthorne, NY 10532

Made in Israel
TARO is a registered trademark of Taro Pharmaceuticals U.S.A., Inc.

Ivermectin

Lotion, 0.5%

Lice Treatment

Original Prescription Strength

Now available without a prescription!

Includes:
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Net Wt. 4 oz (117 g)

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Discard the tube after use.

IVERMECTIN

ivermectin lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-4230
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Ivermectin (UNII: 8883YP2R6D) (Ivermectin - UNII:8883YP2R6D)	Ivermectin	5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
butylated hydroxyanisole (UNII: REK4960K2U)	
castor oil (UNII: D5340Y2I9G)	
cetyl alcohol (UNII: 936JST6JCN)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
cyclomethicone (UNII: NMQ347994Z)	
glycerin (UNII: PDC6A3C00X)	
imidurea (UNII: M629807ATL)	
lanolin alcohols (UNII: 884C3FA9HE)	
methylparaben (UNII: A2I8C7HI9T)	
oleyl alcohol (UNII: 172F2VN8DV)	
olive oil (UNII: 6UYK2W1W1E)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
shea butter (UNII: K49155WL9Y)	
ANHYDROUS TRISODIUM CITRATE (UNII: RS7A450LGA)	
sorbitan tristearate (UNII: 6LUM696811)	
stearyl alcohol (UNII: 2KR89I4H1Y)	

Product Characteristics

Color	WHITE (off-white;tan)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-4230-8	1 in 1 CARTON	01/06/2021	
1		117 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210720	05/06/2020	

Labeler - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(51672-4230)

Revised: 8/2022

Taro Pharmaceuticals U.S.A., Inc.