RID ONE AND DONE- ivermectin lotion Oystershell Consumer Health, 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 an 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 heathcare 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?

1-800-RID-LICE

Distributed by: Oystershell Consumer Health, Inc. 409 Lancaster Ave, Wayne, PA 19087

PRINCIPAL DISPLAY PANEL - 117 g Tube Carton

ORIGINAL PRESCRIPTION STRENGTH

RID

ONE & DONE™

Ivermectin Lotion, 0.5% Lice Treatment

ONE TIME, NO NIT COMBING, 10 MINUTES!

Kills Lice; No Second Application Required

1 Tube NET WT. 4 oz (117 g)



643 2253196-0724-00

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12

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Questions? 1-800-RID-LICE

For single use. Discard the tube after use.

lvermectin Lotion, 0.5% Lice

Original Prescription Strength

Distributed by: Oystershell Consumer Health, Inc. 409 Lancaster Ave, Wavne, PA19 087.

RIDOne & Done' "is a trademark of Oystershell Consumer Health, Inc.

Wade in Israel

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RID ONE AND DONE

ivermectin lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:82392-200

Route of Administration

TOPICAL

| Active ingredictic/Active Molecty | 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: PDC6A3C0OX) | | |
| IMIDUREA (UNII: M629807ATL) | | |
| LANOLIN ALCOHOLS (UNII: 884C3FA9HE) | | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | | |
| OLEYL ALCOHOL (UNII: 172F2WN8DV) | | |
| 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:82392-200- 04 | 1 in 1 CARTON | 08/02/2024 | |
| 1 | | 117 g in 1 TUBE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|---------------------------------|-----------------|---------------|
| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
| Category | Citation | Date | Date |

OTC Monograph Drug | ANDA210720

08/02/2024

Labeler - Oystershell Consumer Health, Inc. (117628199)

Revised: 2/2025

Oystershell Consumer Health, Inc.