

IVERMECTIN- ivermectin lotion
Belmora LLC

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 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 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?

1-888-779-2877

Distributed by:

Belmora LLC, 3033 Wilson Blvd.
Suite 700, Arlington, VA 22201

PRINCIPAL DISPLAY PANEL - 117 g Tube Carton

NDC 27854-334-01

Belmora LLC

SHEA IVERMECTIN

NET WT. 4 oz (117 g)



IVERMECTIN

ivermectin lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27854-334
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: 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:27854-334-01	1 in 1 CARTON	08/12/2024	
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	08/12/2024	

Labeler - Belmora LLC (112753244)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 10/2024

Belmora LLC