VersaPharm Incorporated
2oz. Lindane Shampoo USP, 1%

Rx Only
NDC 61748-400-02
LINDANE SHAMPOO USP, 1%

Each mL contains the following ingredients:
Active: Lindane USP 10 mg
Inactive: acetone, citric acid, polyethylene 60, purified water and triethanolamine lauryl sulfate. The pH may be adjusted with citric acid and/or triethanolamine.

USUAL DOSAGE: See package insert.

SHAKE WELL BEFORE USING

Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature].

ATTENTION PHARMACIST: WHEN DISPENSING, A LINDANE SHAMPOO MEDICATION GUIDE* MUST BE GIVEN TO THE PATIENT AS REQUIRED BY LAW. *Medication guide is provided along with the prescribing information.

Marketed by: VersaPharm Incorporated, Marietta, GA 30062
Manufactured by: AL&S, LLC, DeKalb, MS 38842

Rx Only
NET: 2 fl oz (60 mL)

Do not use if the seal is broken or missing.

VERSAPHARM

PMS 347
REFLEX BLUE
PMS YELLOW
IMPRINT AREA
RESEAL AREA

920 Avenue R Bldg. #200
Grand Prairie, TX 75050 (469)733-1506

Reference:
[251x288]2.000" 0.563"
[266x394]0.563"
[389x383]2.875"
[500x398]0.188"
[552x383]0.375"
[390x217]4.000"

Base

Graphics Proof

Size: 2.000” x 4.000”

PLATINUM PRESS FAX: (469)733-1510

THIS PROOF IS NOT INTENDED FOR COLOR REPRESENTATION. PLEASE REVIEW FOR COPY AND POSITIONING OF GRAPHICS AND TEXT.

APPROVED
REVISE AND RE-PROOF

APPROVAL SIGNATURE/DATE: ____________________________

Rev.
1 10/17/11 EL
2 10/19/11 MC
3 10/31/11 MB
4 10/31/11 MB

Copy

Position

PMS 347 REFLEX BLUE PMS YELLOW IMPRINT AREA RESEAL AREA

#4
Lindane Shampoo should be used with caution in infants, children, the elderly, and patients weighing < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity.

Pthirus pubis (head lice), Pthirus pubis (crotch lice), or Pediculus humanus humanus (clothing lice) lay eggs called nits in your hair. Pthirus pubis (crotch lice) is sometimes referred to as Pubic or crab lice. Lindane Shampoo is mainly for adults and children who weigh > 110 lbs (50 kg). Do not use Lindane Shampoo:

- If you are pregnant, do not use Lindane Shampoo unless you have talked to your doctor about using it. Avoid putting Lindane Shampoo on others if you are pregnant. See the special precautions section.
- If the patient could be pregnant, other treatments may be preferable.
- You cannot use other, safer medicines to treat your lice.
- You should not use Lindane Shampoo if you have had seizures or on the day of death. Seizures and deaths have been reported following Lindane Shampoo usage.
- Lindane Shampoo is contraindicated for patients with known allergy to hexachlorocyclohexane products.
- There have been cases of adverse events reported for Lindane Lotion and Shampoo.

Shampoo exactly as directed:

- Use just enough Lindane Shampoo on your dry hair to wet your scalp. Use up to 20 mL (2 Tbsp) or the amount equivalent to 2 dispensing units. Make sure to lather with other body surfaces.
- Do not wear a shower cap or any covering on your head while you wait for the 4 minutes to pass.
- After 4 minutes has passed, soap up or lather the Lindane Shampoo, and gently scrub your scalp and body. Rinse your hair and body thoroughly. Keep your hair wet for 4 minutes but do not use Lindane Shampoo on your head and neck.
- Soak the applicator cap in the remaining Lindane Shampoo, and discard it. Do not use it again.
- Close the bottle with the leftover Lindane Shampoo and throw the bottle away.

• chloroquine sulfate, pyrimethamine • isoniazid

PRECAUTIONS

Lindane exerts its parasiticidal action by being directly absorbed into the parasites and their ova. Feldmann and Maibach reported a blood level of 290 ng/mL associated with convulsions following the accidental ingestion of a lindane-containing product. There are no clinical dose ranging studies for Lindane Shampoo.

 Sexual contacts should be prescribed Lindane Shampoo only if they either have failed to respond to adequate doses of other approved medications or have never had them before.

How do I use Lindane Shampoo?

- After applying Lindane Shampoo, you should wash your hands well when you are done. Natural latex should be avoided because it is more permeable. Gloves made of nitrile, latex with neoprene, or sheer vinyl are more appropriate. Wash your hands well when you are done.
- The immature central nervous system (as in the fetus) may have increased susceptibility to the effects of the drug. Systemic exposure resulting from Lindane Shampoo applied to hair-covered areas is expected to be lower than that from Lindane Lotion, use to treat scabies.

Pediatric Use

There have been cases of adverse events reported for Lindane Shampoo. The immature central nervous system (as in the fetus) may have increased susceptibility to the effects of the drug. Systemic exposure resulting from Lindane Shampoo applied to hair-covered areas is expected to be lower than that from Lindane Lotion, use to treat scabies. The immature central nervous system (as in the fetus) may have increased susceptibility to the effects of the drug. Systemic exposure resulting from Lindane Shampoo applied to hair-covered areas is expected to be lower than that from Lindane Lotion, use to treat scabies.
DISCLAIMER

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