

DOSAGE AND ADMINISTRATION

Apply a thin layer of Lindane Lotion over all skin from the neck down. One ounce is sufficient for an average adult. Do not prescribe more than 2 ounces for larger adults. Apply only once. Wash off in 8 to 12 hours. Do not retreat. (See boxed WARNINGS.)

Patients should be provided specific information on use of product. (See PRECAUTIONS: Information for Patients and the Medication Guide.) Patients should be instructed on proper use of Lindane Lotion, especially the amount to apply, how long to leave on and the need to avoid retreatment. Patients should be informed that itching occurs after the successful killing of scabies (lice) and continued itching is not necessarily an indication for retreatment with Lindane Lotion.

A **Lindane Lotion Medication Guide** must be given to the patient each time Lindane Lotion is dispensed, as required by law. The Lindane Lotion Medication Guide is an important part of the risk management program for the patient.

HOW SUPPLIED

Lindane Lotion, USP 1% is supplied in patient-size 2 fl oz (60 mL) bottles.

SHAKE WELL BEFORE USING

Store at controlled room temperature, 15 ° – 30 °C (59 ° – 86 °F) [see USP].

REFERENCES

1. Feldmann, R.J. and Maibach, H.I., *Toxicol. Applied. Pharmacol.*, 28:126, 1974.
2. Dale, W.E., Curly, A. and Cueto, C. *Life Sci* 5:47, 1966.
3. Ginsburg, C.M., et al., *J. Pediatr.* 91:6, 998–1000, 1977.
4. FDA AERS database search, January 2003

Rx Only

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PHARMACIST—PATIENT MEDICATION GUIDE PROVIDED BELOW

MEDICATION GUIDE

Lindane (LIHN-dane) Lotion, USP 1%

You must read and follow all instructions before using Lindane Lotion. Read the information you get every time you or a family member get Lindane Lotion. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment. If you have any questions about Lindane Lotion, ask your doctor or pharmacist.

What is the most important information I should know about Lindane Lotion?

Lindane Lotion is a poison if you do not use it the right way. Lindane Lotion goes through your skin and may affect your brain and nerves. Lindane Lotion can cause seizures, also called convulsions, "fits" or epilepsy.

- Seizures and death can happen in people who use Lindane Lotion too much or too often.
- Seizures can happen in some people even if they use Lindane Lotion exactly as directed.

If you or a family member has a seizure while using Lindane Lotion, get emergency help right away.

- Do not use Lindane Lotion unless:
 - You have scabies and were treated with another medicine that did not work for you, or
 - You cannot use other safer medicines to treat your scabies.
- Do not use Lindane Lotion more than 1 time to treat an attack of scabies. Do not use Lindane Lotion to treat a second attack of scabies that comes soon after the first episode. Using it more than 1 time can cause seizures and death. No one knows a safe time to reuse Lindane Lotion. Even if you still itch after using Lindane Lotion, do not use more or use it again. Scabies (bugs) can make your skin itch for a few weeks even after all of the bugs are dead.
- Do not use more Lindane Lotion than your doctor tells you.
- Do not keep Lindane Lotion on your skin for more than 8 to 12 hours.
- Do not put Lindane Lotion in your mouth because it is a poison if taken by mouth. If you get Lindane Lotion in your mouth or swallow Lindane Lotion, call your area Poison Control Center right away and get emergency help.

What is Lindane Lotion?

Lindane Lotion is a medicine that is used to treat scabies. It kills scabies and their eggs. Scabies are very small bugs that crawl under your skin, lay eggs, and cause severe itching. Lindane Lotion goes through your skin and kills the scabies and their eggs. Lindane Lotion is used only after safer medicines have not made your scabies go away. The only time Lindane Lotion is used first is when someone cannot use safer medicines, which may include permethrin and crotamiton.

Lindane Lotion is mainly for adults and children who weigh at least 110 pounds. If you weigh less than 110 pounds, use Lindane Lotion only if your doctor thinks it is really needed. People who weigh less than 110 pounds and the elderly have higher chances for side effects because more lindane may go through their skin.

Who should not use Lindane Lotion?

Do not use Lindane Lotion:

- if you do not have scabies. Lindane Lotion does not stop you from getting scabies. Lindane Lotion only kills the scabies you already have.
- if you have or have ever had seizures, also called convulsions, "fits" or epilepsy, especially if they have been hard to control.
- if you used Lindane Lotion in the past few months. You should see your doctor if you think you need another treatment.
- unless it is the only medicine you can use for scabies.
- if you had a bad reaction to Lindane Lotion before. **Do not use Lindane Lotion again.**
- if you have open sores or crusted (scabby) sores on your skin, or lots of broken skin.
- if you have head or body lice. These need a different medicine that you use in a different way.
- if you are allergic to Lindane Lotion or any of its ingredients. The active ingredient is lindane. See the end of this Medication Guide for a list of all the ingredients in Lindane Lotion.
- if you need to treat a premature or young baby. More lindane can go through the skin of babies and go to their brains where it can harm them.
- while you are breast-feeding. Lindane Lotion can get in your milk and be fed to your baby. Lindane Lotion on your skin can also go to your baby. Your baby may get sick. Ask your doctor for a safer medicine. If you use Lindane Lotion, pump your breast milk and throw away the milk for at least 24 hours after using the medicine. During this time, feed your baby formula or breast milk you stored from before you used Lindane Lotion.

Tell your doctor if you:

- used Lindane Lotion in the past few months.
- ever had a seizure or problem that could increase your chances of getting a seizure (like a head injury, tumor in your brain or spinal cord, cirrhosis of the liver, or heavy alcohol drinking.)
- have HIV or AIDS. Lindane Lotion may cause seizures even if you never had them before.
- are pregnant. Lindane Lotion can reach your baby and may harm it. Ask your doctor for a safer medicine. Use Lindane Lotion only if needed.
- have a sexual partner. Your partner should get checked and treated for scabies so they don't give them back to you. Don't share your Lindane Lotion with your partner.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may increase your chances of having a seizure if you take them while using Lindane Lotion. Especially, tell your doctor if you take medicines called sedatives (drugs to help you sleep).

How do I use Lindane Lotion?

Before you put it on:

- **Make sure you know how to use it exactly as your doctor prescribes.**
- If you are putting Lindane Lotion on another person, wear special gloves made of nitrile, latex with neoprene, or sheer vinyl. **Do not use natural latex gloves because more lindane can go through that kind of glove. Wash your hands well when you are done.**
- Make sure your skin is clean and does not have any other lotion, cream, or oil on it. Oils can make Lindane Lotion go through your skin faster and may increase the risk of seizures.

- Wait for at least 1 hour after bathing or showering before you put Lindane Lotion on your skin. Wet or warm skin can make the Lindane Lotion go through your skin faster and may increase the risk of seizures.

When you put it on:

- Shake the bottle of Lindane Lotion well.
- Put Lindane Lotion under your fingernails, because the scabies really like to stay there. Trim your fingernails short. Use a toothbrush to get the Lindane Lotion under your fingernails. Wrap this toothbrush in paper and throw this toothbrush away. Do not use it in your mouth.
- Put a very thin layer of the Lindane Lotion on your skin from the neck down. You may have some Lindane Lotion left in the bottle.
- Do not cover over the Lindane Lotion on your skin with anything that does not breathe, like diapers with a plastic lining, plastic clothes, tight clothes, or blankets.
- Close the bottle with the leftover Lindane Lotion and throw it away in a trash can **out of the reach of children.**

When you are supposed to wash it off:

- Wash the Lindane Lotion off your skin after 8 to 12 hours. You must wash the Lindane Lotion off your body completely. Use warm, but not hot water. Lindane Lotion will not kill any more scabies after 8 to 12 hours. After 8 to 12 hours, Lindane Lotion can cause serious health problems, such as seizures and death.

After you wash off the Lindane Lotion:

- All recently worn clothing, underwear, pajamas, used sheets, pillowcases, and towels should be washed in very hot water or dry-cleaned.
- Do not use Lindane Lotion again. If you think you need to use it again, you must check with your doctor to find out when it is most safe.

You may still itch after you use Lindane Lotion. **This does not mean you need more Lindane Lotion.** Even after all the scabie bugs are dead, they can still make your skin itch for a few weeks. Lindane Lotion sometimes makes this itch even worse. Talk to your doctor about things you can do to soothe the itch.

What should I avoid while using Lindane Lotion?

- Do not get Lindane Lotion in your eyes. If you do, rinse your eyes with water right away. Get medical help if your eyes keep hurting.
- Do not let your skin touch other people's skin while you have Lindane Lotion on. Make sure your skin does not touch your baby or small child.
- If you are pregnant, do not use Lindane Lotion, or apply Lindane Lotion to others unless it is needed and you have talked to your doctor about using it. See the special glove advice below if you have to put Lindane Lotion on others.
- Do not use oils on your skin or hair just before or after using Lindane Lotion. Oils include skin lotions and moisturizers, and oil-based hair products and conditioners.
- Do not get Lindane Lotion on your hands if you are putting it on someone else. Wear special gloves made of nitrile, latex with neoprene, or sheer vinyl. Do not use natural latex gloves. Wash your hands well when you are done.

What are the possible side effects of Lindane Lotion?

Lindane Lotion may cause serious side effects such as seizures (convulsions, fits) or death (See the section, "What is the most important information I should know about Lindane Lotion?"). Lindane Lotion can also make you feel sleepy, dizzy, or can cause body shaking that you cannot control.

The most common side effects of Lindane Lotion are:

- Itching skin
- Burning skin
- Dry skin
- A skin rash

These are not all of the possible side effects of Lindane Lotion. For more information, ask your doctor or pharmacist.

General Information about Lindane Lotion:

Medicines are sometimes prescribed for purposes other than those listed in Medication Guides. Do not use Lindane Lotion for any condition for which it was not prescribed. Do not give Lindane Lotion to other people, even if they have the same symptoms that you have. It may harm them. **Keep Lindane Lotion and all medicines out of the reach of children.**

This Medication Guide summarizes the most important information about Lindane Lotion. If you want more information, talk with your doctor. You can ask your doctor or pharmacist for information about Lindane Lotion that is written for health professionals.

What are the ingredients in Lindane Lotion?

Active Ingredient: Lindane.

Inactive Ingredients: 2-amino-2-methyl-1-propanol, carrageenan, cetyl alcohol, cocoa butter, glyceryl monostearate, methylparaben, propylene glycol, propylparaben, purified water, stearic acid and trolamine.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

This medication is available only by a prescription from your doctor.

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