

If accidental ingestion occurs, prompt gastric lavage should be instituted. However, since oils enhance absorption, saline cathartics for intestinal evacuation should be given rather than oil laxatives. If central nervous system manifestations occur, they may be antagonized by the administration of pentobarbital, phenobarbital, or diazepam.

DOSAGE AND ADMINISTRATION

Most patients will require only 1 ounce of Lindane Shampoo. Based on the length and density of hair, some patients may require 2 ounces of Lindane Shampoo.

Apply shampoo directly to dry hair without adding water. Work thoroughly into the hair and allow to remain in place for 4 minutes only. Special attention should be given to the fine hairs along the neck. After 4 minutes, add small quantities of water to hair until a good lather forms. Immediately rinse all lather away. Avoid unnecessary contact of lather with other body surfaces. Do not prescribe more than 2 ounces for larger adults. Do not retreat. (See boxed WARNINGS.)

Patients should be provided specific information on use of product. (See PRECAUTIONS: Information for Patients and Lindane Shampoo Medication Guide.)

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

HOW SUPPLIED

Lindane Shampoo, 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

Product No.: 8834

Manufactured By: Morton Grove Pharmaceuticals, Inc., Morton Grove, IL 60053

A50-8834-60

ISS. 04-07

PHARMACIST—PATIENT MEDICATION GUIDE PROVIDED BELOW

MEDICATION GUIDE

Lindane (LIHN-dane) Shampoo, USP 1%

You must read and follow all instructions before using Lindane Shampoo. Read the information you get every time you or a family member get Lindane Shampoo. 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 Shampoo, ask your doctor or pharmacist.

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

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

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

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

- Do not use Lindane Shampoo unless
- You have lice and another medicine did not work for you, or
- You cannot use other, safer medicines to treat your lice
- Do not use Lindane Shampoo more than 1 time to treat an attack of lice. Do not use Lindane Shampoo to treat a second attack that comes soon after the first episode. No one knows a safe time to reuse Lindane Shampoo. Even if you still itch even after using Lindane Shampoo, do not use more or use it again. Lice (bugs) can make you itch for some time even after all of the bugs are dead.
- Do not use more Lindane Shampoo than your doctor tells you.

- Do not keep Lindane Shampoo on your hair for more than 4 minutes.
- Do not put Lindane Shampoo in your mouth because it is a poison if taken by mouth. If you get Lindane Shampoo in your mouth or swallow Lindane Shampoo, call your area Poison Control Center right away and get emergency help.

What is Lindane Shampoo?

Lindane Shampoo is a medicine that is used to treat lice. It kills lice and their eggs. Lice are very small bugs that attach to the skin on your head or pubic (crotch) area and lay eggs called nits in your hair. Some people call crotch lice "crabs". Lice can cause severe itching. Lindane Shampoo gets into the lice and the nits and kills them. It also goes through your skin. Lindane Shampoo is used only after safer medicines have not made your lice go away. The only time Lindane Shampoo is used first is when someone cannot use safer medicines, which may include permethrin and crotamiton.

Lindane Shampoo is mainly for adults and children who weigh at least 110 pounds. If you weigh less than 110 pounds use Lindane Shampoo 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 Shampoo?

Do not use Lindane Shampoo:

- if you do not have lice. Lindane Shampoo does not stop you from getting lice. Lindane Shampoo only kills the lice 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 have used Lindane Shampoo in the past few months. You should see your doctor if you think that you need another treatment.
- unless it is the only medicine you can use for lice.
- if you had a bad reaction to Lindane Shampoo before. **Do not use Lindane Shampoo again.**
- if you have open sores or crusted (scabby) sores on the skin around your head and neck, or lots of broken skin.
- if you need to treat a premature or young baby. More of the applied Lindane can go through the skin of babies and go to their brains where it can harm them.
- if you have scabies. These need a different medicine that you use in a different way.
- if you are allergic to Lindane Shampoo 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 Shampoo.
- while you are breast-feeding. Lindane Shampoo can get in your milk and may be fed to your baby. Your baby may get sick. Ask your doctor for a safer medicine. If you use Lindane Shampoo, pump your breast milk and throw the milk away for at least 24 hours after using the medicine. During this time, feed your baby formula or breast milk that you stored from before you used Lindane Shampoo.

Tell your doctor if you:

- used Lindane Shampoo 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 Shampoo may cause seizures even if you never had them before.
- are pregnant. Lindane Shampoo can reach your baby and may harm it. Ask your doctor for a safer medicine. Use Lindane Shampoo only if needed.
- have a sexual partner and your lice (crabs) are in your pubic (crotch) area. Your partner should get checked and treated for lice so they don't give them back to you. Don't share your Lindane Shampoo 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 Shampoo. Especially tell your doctor if you take medicines called sedatives (drugs to help you sleep).

How do I use Lindane Shampoo?

Before you put it on:

- **Make sure you know how to use it exactly as your doctor prescribes.**

- If you are putting Lindane Shampoo 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.** Keep the gloves on until the Lindane Shampoo is washed out of your hair. **Wash your hands well when you are done.**
- Make sure your hair and skin on your head and neck do not have any other shampoo, cream, or oil on it. Oils can make the Lindane Shampoo go through your skin faster and may increase the risk of seizures.

When you put it on:

- Shake the bottle of Lindane Shampoo well.
- Make sure your hair is clean and dry before using Lindane Shampoo, but do not wash your hair within 1 hour before using Lindane Shampoo. Use regular shampoo without conditioner and dry your hair.
- Use just enough Lindane Shampoo on your dry hair to wet your hair and scalp. Do not add water to your hair at this time. Also, put Lindane Shampoo on the short hairs at the back of your neck.
- Keep Lindane Shampoo on your hair for 4 minutes. Use a watch or clock to time yourself.
- Do not wear a shower cap or any covering on your head while you wait for the 4 minutes to pass.
- Close the bottle with the leftover Lindane Shampoo and throw it away in a trash can **out of the reach of children.**

When you are supposed to wash it off:

- After 4 minutes has passed, soap up or lather the Lindane Shampoo. Use a small amount of warm water to do this. Hot water is not safe. Then wash the Lindane Shampoo off your head. Again, use warm, but not hot water. Do not leave any Lindane Shampoo on your head or hair. It will not kill more of the lice and may continue to go through your skin and cause serious problems, such as seizures.

After you wash off Lindane Shampoo:

- Dry your hair with a towel. Use a special comb called a nit comb or tweezers to remove the dead nits (lice eggs) from your hair. Someone else will probably have to do this for you.
- All recently worn clothing, underwear, pajamas, hats, used sheets, pillowcases, and towels should be washed in very hot water or dry-cleaned.
- Do not use Lindane Shampoo again. If you think you need to use it again, you must check with your doctor to find out if and when it is most safe.

You may still itch after you have used Lindane Shampoo. This does not mean you need more Lindane Shampoo. Even after all the lice (bugs) are dead, they can still make your skin itch for a long time. Lindane Shampoo 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 Shampoo?

- Do not get Lindane Shampoo in your eyes. If you do, rinse your eyes with water right away. Get medical help if your eyes keep hurting.
- Do not get Lindane Shampoo on your hands. 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.
- 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 glove advice above if you have to put Lindane Shampoo on others.
- Do not use oils on your skin or hair, just before or after using Lindane Shampoo. Oils include oil-based hair products and conditioners.

What are the possible side effects of Lindane Shampoo?

Lindane Shampoo 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 Shampoo?"). Lindane Shampoo can also make you feel sleepy, dizzy, or can cause body shaking that you cannot control.

The most common side effects of Lindane Shampoo are:

- Itching skin
- Burning skin

- Dry skin
- A skin rash

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

General Information about Lindane Shampoo:

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

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

What are the ingredients in Lindane Shampoo?

Active Ingredient: Lindane.

Inactive Ingredients: triethanolamine lauryl sulfate, polysorbate 60, hydrochloric acid, acetone and purified water.

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

Lindane is only available by a prescription from your doctor.

Product No.: 8834

Manufactured By: Morton Grove Pharmaceuticals, Inc., Morton Grove, IL 60053

A50-8834-60

ISS. 04-07

Revised: 08/2007

Distributed by: Morton Grove Pharmaceuticals, Inc.