

Status of Lindane (February 2004)

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Old History (a)

- **1947: Approved for pediculosis and scabies**
- **1994: The innovator's NDAs were withdrawn but several generic products were available**
- **1995: Evaluation of adverse event reports**

Old History (b)

- **1996: Labeling was revised to describe second-line therapy**
 - **If cannot tolerate other approved Tx or**
 - **Have failed Tx with other approved Tx**
- **Increased warnings**

Other Approved Products

- **Scabies**
 - **Permethrin**
 - **Crotamiton (Eurax)**
- **Lice**
 - **Pyrethrum/piperonyl butoxide**
 - **Permethrin (Nix)**
 - **Malathion (Ovide)**

Recent History

- **2002-2003: Reevaluation**
 - Reviewed adverse event reports
 - Reviewed the literature
 - Reviewed new nonclinical data

Labeling Changes in 2003

- **Boxed warning**
- **Lindane product package sizes limited to 1 and 2 oz for single Tx**
- **Medication Guide**
 - **Must be dispensed by the pharmacist with each new Rx**

Black Box Warning (a)

- **WARNINGS:**
- **Lindane Shampoo should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of lice. (See INDICATIONS AND USAGE.)**

Black Box Warning (b)

- **Neurologic Toxicity**
- **Seizures and deaths have been reported following Lindane Shampoo use with repeat or prolonged application, but also in rare cases following a single application used according to directions.**

Black Box Warning (c)

- **Lindane shampoo should be used with caution for infants, children, the elderly, and individuals with other skin conditions (e.g, atopic dermatitis, psoriasis) and in those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity.**

Contraindications

- **Lindane Shampoo is contraindicated in premature infants and individuals with known uncontrolled seizure disorders.**

Proper Use

- **Instruct patients on proper use of Lindane shampoo, the amount to apply, how long to leave it on, and avoiding retreatment. Inform patients that itching occurs after the successful killing of lice and is not necessarily an indication for retreatment with Lindane Shampoo (See DOSAGE AND ADMINISTRATION)**

Current Issues (a)

- **Most serious adverse events reported are due to misuse**
- **Potential toxicity is emphasized in product labels**
- **Providers and patients are informed about risks and how to minimize them**

Current Issues (b)

- **Post-treatment itch is described for scabies**
- **Medical benefits outweigh risks when used as directed**

Other Activities

- **Will follow up on effectiveness of new labeling**
- **Nominated lindane for a dose-ranging study**
 - **Perhaps a lower amount of lindane might be effective**
- **Encouraging sponsors of alternative, less toxic, products**

Website for Information

<http://www.fda.gov/cder/drug/infopage/lindane>