

SAME SIZE ARTWORK
LEAFLET SIZE: 140 mm x 176 mm

20 mm

22 mm

22 mm

Clinical Pharmacology

Pharmacodynamics: Lindane is a central nervous system (CNS) stimulant when absorbed systemically. Following absorption through the chitinous exoskeleton of arthropods, lindane is presumed to stimulate the nervous system, resulting in convulsions and death.

Pharmacokinetics:

Absorption

The absorption of lindane through the skin is highly variable. Although the incidence of adverse effects appears to be higher in infants and young children than in adults, there have been no studies to demonstrate that children absorb more lindane than adults.

Lotion – In one study, a mean peak blood concentration of 3 nanograms per mL occurred in infants and children 6 hours after total body application of lindane lotion for scabies.

Distribution

Lindane is highly lipid- soluble and is stored in adipose tissue and other lipophilic tissue. Lindane is also stored in the white matter of the brain and may persist in low levels for up to 2 weeks following topical application.

Metabolism

Decreased half-life and increased clearance of antipyrine when preceded by a topical lindane 1% application of 12 hours duration. This suggests that lindane induces microsomal drug metabolism.

Elimination Half-Life

17.9 to 21.4 hours

Packaging/Pack Size: Bottle of 100ml.

Storage condition

Store below 30°C. Protect from light.

Shelf-Life

48 months

Date of Revision:

1 December 2019

MAL 19912733XZ

Product Registration Holder

Glenmark Pharmaceuticals
(Malaysia) Sdn Bhd (660397-W)
D-31-02, Menara Suezcap 1,
No. 2, Jalan Kerinchi,
59200 Kuala Lumpur, Malaysia

Manufactured by:
glenmark

PHARMACEUTICALS LTD.
Plot No. E-37, 39, D-Road,
MIDC, Satpur, Nashik - 422 007,
Maharashtra State, India.
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For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Scaboma™

LOTION

SPACE FOR
PHARMACODE

Composition

Lindane USP 1% w/v
Aqueous Base q.s.

Description:

A printed carton containing an insert & labelled sealed amber coloured glass bottles containing a white lotion with rose perfume.

Therapeutic indications

SCABOMA lotion is indicated for the treatment of scabies (infestations of *Sarcoptes scabiei*) in patients who:

1. Cannot tolerate other approved therapies, OR
2. Have failed treatment with other approved therapies.

Dosage and Administration

For Scabies (*Sarcoptes Scabiei*)

- 1) It is recommended 30ml of SCABOMA Lotion applied in a thin layer to all areas of the body from the neck down and thoroughly washed off after 8 hours. SCABOMA should not be applied immediately after a bath or shower and should not be used by persons with extensive dermatitis, or in pregnant or lactating women.
- 2) The lotion should be applied thinly and rubbed in thoroughly from the neck down to the soles of the feet, with special attention under nail and to the hands, feet and interdigital areas. Avoid applying SCABOMA to open cuts or excoriations.
- 3) The mite does not infest areas of sebaceous gland activity in adults or children, and the face and scalp need not be treated. However, scabies may affect the head in infants.
- 4) The lotion should be left on for 8 to 12 hours and removed by thorough washing.
- 5) One application is usually curative although many patients exhibit persistent pruritus after treatment. It is not known how soon after SCABOMA administration that a second dose can safely be readministered. Retreatment is not recommended.

Pediatric Use: Animal data demonstrated increased risk of adverse events in the young across species. Pediatric patients have a higher surface to volume ratio and may be at risk of greater systemic exposure when Lindane Lotion is applied to the body. Infants and children may be at an even higher risk due to immaturity of organ systems such as skin and liver. SCABOMA Lotion should be used with extreme caution in patients who weigh less than approximately 110 lbs (50 kg) and especially in infants

Geriatric Use: There have been no studies of Lindane Lotion in the elderly.

ICONGRAPHICS CODE:

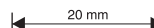
PANTONE SHADE



PANTONE
BLACK
PROCESS C

Supersedes
Artwork Code:
PE50656

PHARMACODE:



Route of administration:

External application topical use.

Contraindications

- SCABOMA Lotion is contraindicated for premature infants because their skin may be more permeable than that of full term infants and their liver enzymes may not be sufficiently developed to metabolize Lindane.
- SCABOMA Lotion is also contraindicated for patients with crusted (Norwegian) scabies and other skin conditions (e.g. atopic dermatitis, psoriasis) that may increase systemic absorption of the drug.
- SCABOMA Lotion is contraindicated for patients with known uncontrolled seizure disorders and for individuals with a known sensitivity to the product or any of its components.

Warnings

WARNINGS:

Lindane Lotion should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of scabies.

Neurologic Toxicity

Seizures and deaths have been reported following Lindane Lotion use with repeat or prolonged application, but also in rare cases following a single application used according to directions. Lindane lotion 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 Lotion is contraindicated in premature infants and individuals with known uncontrolled seizure disorders.

- NOT first-line agent
- Use only as directed
- CNS toxicity may be greater in the young, use with extreme caution in infants, children and pregnant and nursing mothers.
- Avoid contact with eyes or mucous membranes
- Avoid inflamed or excoriated skin
- Avoid simultaneous use with other creams, ointments, or oils
- Condition which may increase the risk of seizure (eg. HIV, history of head trauma or prior seizure, CNS tumor, excessive alcohol consumption)
- Elderly
- Concomitant medications which lower the seizure threshold
- Individuals weighing less than 50 Kg
- Just put a very thin layer for the Lindane Lotion.
- Wash the Lindane lotion of your skin after 8 to 12 hours.
- You may still itch after you use SCABOMA Lotion. Even after all the scabies bugs are dead, they can still make your skin itch for a few weeks. This does not mean you need more SCABOMA Lotion.
- Avoid retreatment with lindane.

Drug Interactions

Oils may enhance absorption of Lindane, therefore, patients or caregivers applying SCABOMA Lotion should be warned about simultaneous use of creams, ointments, or oils.

The following drug interactions and/or related problems have been selected on the basis of their potential clinical significance

(possible mechanism in parentheses where appropriate) – not necessarily inclusive (>> = major clinical significance):

Skin, scalp or hair preparation, other, such as creams, lotions, ointments or oils (simultaneous application may increase the percutaneous absorption of lindane).

Pregnancy

Adequate and well-controlled studies in humans have not been done. Because lindane is absorbed through the skin and has the potential of causing CNS toxicity, some clinicians do not recommend the use of lindane during pregnancy. If lindane is used, however, the recommended dosage should not be treated more than twice during pregnancy. Studies in animals have not shown that lindane causes adverse effects on the fetus.

For breast feeding, problems in human have not been documented; however, lindane is systematically absorbed and is distributed into breast milk. Although the concentrations found in human blood following topical application of lindane make it unlikely that breast milk will contain amounts of lindane sufficient to cause toxicity, an alternate method of feeding the infant should be used for 2 days.

Undesirable effects

Lindane Lotion is absorbed through the skin and has the potential for CNS toxicity, especially in infants, children and possibly the elderly.

The following side effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate) – not necessarily inclusive.

Those indicating need for medical attention

Incidence rare:

Skin irritation not present before therapy – If Lindane is applied incorrectly or repeatedly, the incidence of skin irritation is increased: skin rash.

Symptoms of CNS toxicity:

Convulsions; dizziness, clumsiness or unsteadiness; fast heartbeat, muscle cramps; nervousness, restlessness or irritability; vomiting.

Those indicating need for medical attention, if they occur and continue or are bothersome after medication is discontinued. Itching of skin- acquired sensitivity to mites and their products may continue for one to several weeks.

Other adverse effects in single patients that have been associated with lindane are disseminated intravascular coagulation and subsequent death after oral ingestion and aplastic anaemia after prolonged topical exposure (twice daily application for three weeks).

Overdose

Symptoms of overdose

Mild to moderate toxicity: vomiting, headache, nausea, dizziness, diarrhea, and tremor.

Severe toxicity: Seizures, CNS depression, agitation, ataxia, hypotension, respiratory depression, metabolic acidosis, and coma. Children appear to be more susceptible to the toxic effects of lindane and more likely to manifest severe effects.

For treatment of toxicity:

If accidental ingestion occurs, it may be life threatening and prompt gastric lavage is recommended.

Since oils favour absorption, saline cathartics should be administered rather than oily cathartics for intestinal evacuation.

If CNS manifestations occur, they may be treated by the administration of pentobarbital, Phenobarbital or diazepam.

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PHARMACODE: