

LIENDREX- pyrethrum extract, piperonyl butoxide shampoo
Menper Distributors Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ACTIVE INGREDIENTS

PYRETHINS 0.30%

PIPERONYL BUTOXIDE 4%

PURPOSE

LICE TREATMENT

USES: FOR THE TREATMENT OF HEAD, BODY, PUBIC (CRAB) LICE.

WARNINGS

FOR EXTERNAL USE ONLY.

ALLERGY ALERT: USE WITH CAUTION ON PERSONS WITH ALLERGIC TO RAGWEED.

DO NOT USE

- NEAR OR PERMIT CONTACT WITH EYES OR MUCOUS MEMBRANES, SUCH AS INSIDE THE NOSE, MOUTH, OR VAGINA AS IRRITATION MAY OCCURE.

WHEN USING THIS PRODUCT

- KEEP OUT OF EYES WHEN RINSING HAIR.
- CLOSE EYES TIGHTLY AND DO NOT OPEN UNTIL PRODUCT IS RINSED OUT.
- PROTECT EYES WITH WASHCLOTH, TOWEL OR OTHER SUITABLE MATERIAL OR BY SIMILAR METHOD.
- IF PRODUCT GETS INTO EYES, IMMEDIATELY FLUSH WITH WATER.

STOP USE AND ASK A DOCTOR IF

- SKIN IRRITATION OR INFECTION IS PRESENT OR DEVELOPS.
- INFESTED EYEBROWS OR EYELASHES OCCURS.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

IMPORTANT: READ WARNINGS AND OTHER INFORMATION BEFORE USING.

- SHAKE WELL BEFORE USING.
- USE ON DRY HAIR.
- APPLY TO AFFECTED AREA UNTIL ALL HAIR IS THOROUGHLY WET WITH PRODUCT.
- ALLOW PRODUCT TO REMAIN ON FOR 10 MINUTES BUT NO LONGER.
- ADD SUFFICIENT WARM WATER TO FORM A LATHER AND SHAMPOO AS USUAL.
- RINSE THOROUGHLY.
- A FINE TOOTH COMB OR SPECIAL LICE/NIT-REMOVAL COMB MAY BE USED TO HELP REMOVE DEAD LICE AND THEIR EGGS (NITS) FROM HAIR.
- A SECOND TREATMENT MUST BE DONE IN 7 TO 10 DAYS TO KILL ANY NEWLY HATCHED LICE.

OTHER INFORMATION

- STORAGE: PROTECT FROM FREEZING AND EXCESSIVE HEAT.

- DO NOT REUSE ORIGINAL CONTAINER.

OTHER INGREDIENTS

WATER, PEG-80 SORBITAN LAURATE, COCAMIDOPROPYL BETAINE, POLYSORBATE 80, SODIUM TRIDECETH SULFATE, SODIUM LAUROAMPHOACETATE, SODIUM LAURETH-13 CARBOXYLATE, CITRIC ACID AND TETRASODIUM EDTA.

Drug Facts

Active ingredients **Purpose**

Pyrethrins 0.30% Lice Treatment

Piperonyl Butoxide 4% Lice Treatment

Uses For the treatment of Head, Body, Pubic (Crab) Lice

Warnings For external use only

Allergy Alert: use with caution on persons allergic to ragweed

Do not use

- near or permit contact with eyes or mucous membranes, such as inside the nose, mouth, or vagina as irritation may occur

When using this product

- keep out of eyes when rinsing hair
- close eyes tightly and do not open until product is rinsed out
- protect eyes with washcloth, towel or other suitable material or by a similar method
- if product gets into eyes, immediately flush with water

Stop use and ask a doctor if

- skin irritation or infection is present or develops
- infested eyebrows or eyelashes occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately

NDC 53145-0308-04

INSTRUCCIONES EN ESPAÑOL INCLUIDAS

Drug Facts (continued)

Directions Important: read Warnings and Other Information before using

- shake well before using
- use on DRY hair
- apply to affected area until all hair is thoroughly wet with product
- allow product to remain on for 10 minutes but no longer
- add sufficient warm water to form a lather and shampoo as usual
- rinse thoroughly
- a fine tooth comb or special lice/nit-removing comb may be used to help remove dead lice and their eggs (nits) from hair
- a second treatment must be done in 7 to 10 days to kill any newly hatched lice

Other Information

- Storage: Protect from freezing and excessive heat
- Do not reuse original container

Other Ingredients

Water, PEG-80 Sorbitan Laurate, Cocamidopropyl Betaine, Polysorbate 80, Sodium Trideceth Sulfate, Sodium Lauroamphoacetate, Sodium Laureth-13 Carboxylate, Citric Acid and Tetrasodium EDTA.

Distributed By:
MENPER DISTRIBUTORS, INC.
6500 N.W. 35th Street., Miami, FL 33147

LIENDREX

pyrethrum extract, piperonyl butoxide shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53145-308
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PIPERONYL BUTOXIDE (UNII: LWK91TU9AH) (PIPERONYL BUTOXIDE - UNII:LWK91TU9AH)	PIPERONYL BUTOXIDE	4 g in 100 mL
PYRETHRUM EXTRACT (UNII: ZUM06L90GV) (PYRETHRUM EXTRACT - UNII:ZUM06L90GV)	PYRETHRUM EXTRACT	0.3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
PEG-20 SORBITAN ISOSTEARATE (UNII: X958PZJ9ON)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	

POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM TRIDECETH SULFATE (UNII: E827ILX331)	
SODIUM LAURO AMPHO ACETATE (UNII: SLK428451L)	
SODIUM LAURETH-13 CARBOXYLATE (UNII: 795TQP1655)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE SODIUM (UNII: MP1J8420LU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53145-308-04	120 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358G	01/01/2013	

Labeler - Menper Distributors Inc. (101947166)

Revised: 3/2013

Menper Distributors Inc.