LICEMD TREATMENT- pyrethrum extract and piperonyl butoxide gel Reckitt Benckis er LLC

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.

LiceMD[®]
Treatment Gel

Drug Facts

Active ingredients	Purpose
Piperonyl butoxide (4%)	Lice treatment
Pyrethrum extract (equivalent to pyrethrins 0.33%)	Lice treatment

Uses

treats head, pubic (crab), and body lice

Warnings

For external use only

Do not use

- near eyes
- inside nose, mouth or vagina
- on lice in eyebrows or eyelashes. See a doctor if lice are present in these areas.

Ask a doctor before use if you are allergic to ragweed. May cause breathing difficulty or an asthmatic attack.

When using this product

- keep eyes tightly closed and protect eyes with a washcloth or towel
- if product gets in eyes, flush with water right away
- scalp itching or redness may occur

Stop use and ask a doctor if

- breathing difficulty occurs
- eve irritation occurs
- skin or scalp irritation continues or infection occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control center right away.

Directions

Important: Read warnings before use.
 Read leaflet inside carton for complete directions before use.
 Adults and children 2 years and over:
 Inspect

check each household member with a magnifying glass in bright light for lice/nits (eggs)

- look for tiny nits near scalp, beginning at back of neck and behind ears
- examine small sections of hair at a time
- unlike dandruff which moves when touched, nits stick to the hair
- if either lice or nits are found, treat with this product

Treat

- apply this product thoroughly to dry hair or other affected area. For head lice, first apply behind ears and to back of neck.
- allow this product to remain on hair or other affected area for 10 minutes, but no longer
- wash area thoroughly with warm water and soap or shampoo
- for head lice, towel dry hair and comb out tangles

Remove lice and their eggs (nits)

- use a fine-tooth comb or the special lice/nit comb. Remove any remaining nits by hand (using a throw-away glove).
- hair should remain slightly damp while removing nits
- if hair dries during combing, dampen slightly with water
- for head lice, part hair into sections. Do one section at a time starting on top of head. Longer hair may take 1 to 2 hours.
- lift a 1 to 2 inch wide strand of hair. Place comb as close to scalp as possible and comb with a firm, even motion away from scalp.
- pin back each strand of hair after combing
- clean comb often. Wipe nits away with tissue and discard in a plastic bag. Seal bag and discard to prevent lice from coming back.
- after combing, thoroughly recheck for lice/nits. Repeat combing if necessary.
- check daily for any lice/nits that you missed
- a second treatment with this product must be done in 7 to 10 days to kill any newly hatched lice
- if infestation continues, see a doctor for other treatments

Children under 2 years: ask a doctor

Other information

- store at 20-25°C (68-77°F). Avoid excessive heat.
- keep carton for important product information
- see leaflet inside carton for additional information

Inactive ingredients

butylated hydroxytoluene, carboxymethylcellulose sodium, dimethicone, fragrance, hydroxyethylcellulose, methylchloroisothiazolinone, methylisothiazolinone, petroleum distillates, water

Questions?

1-866-252-5327.

You may also report side effects to this phone number.

LiceMD® Comb

Directions

For Head Lice

Please read the leaflet for complete directions before use.

Use AFTER LiceMD treatment gel and shampooing steps.

- comb out the dead lice, eggs, and nits with the enclosed LiceMD comb. **Please read the entire leaflet for complete directions. This step is very important.**
- start at the top of the head, comb one section at a time and it is important to get the teeth of the comb very close to the scalp. Combing can take over an hour.
- if hair dries before combing, dampen slightly with warm water
- soak all combs, bobby pins, and hair clips in hot water [above 54°C (130°F)] after combing
- check daily for any lice/nits that you have missed

Throw-Away Gloves

- 100% nitrile
- powder-free
- latex-free
- non-sterile
- single-use

Dist. by: Reckitt Benckiser Parsippany, NJ 07054-0224

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

LiceMD[®]
TREATMENT GEL

SATISFACTION GUARANTEED 100% GUARANTEE OR YOUR MONEY BACK**

NDC 63824-908-00

LiceMD[®] TREATMENT GEL

Pyrethrum Extract (Equivalent to 0.33% Pyrethrins) with Piperonyl Butoxide 4% Lice Treatment

KILLS LICE & ELIMINATES
100% of THEIR EGGS*

TREAT - kill lice

COMB - eliminate 100% lice eggs

CONTAINS:

1 Lice Killing Gel 4 FL OZ (118mL) 1 Comb

2 Pairs of

Throw-Away

Gloves

*The LiceMD Comb eliminated 100% lice eggs in laboratory testing



NDC 63824-908-00

LiceMD®

Pyrethrum Extract
(Equivalent to 0.33% Pyrethrins)
with Piperonyl Butoxide 4%
Lice Treatment

KILLS LICE & ELIMINATES 100% of THEIR EGGS*

TREAT - kill lice

COMB - eliminate 100% lice eggs

CONTAINS:

- 1 Lice Killing Gel 4 FL OZ (118mL)
- 1 Comb
- 2 Pairs of Throw-Away Gloves
- * The LiceMD Comb eliminated 100% lice eggs in laboratory testing



LiceMD® Treatment Gel

Drug Facts

Active ingredients Purpose
Piperonyl butoxide (4%)....Lice treatment
Pyrethrum extract (equivalent to
pyrethrins 0.33%)......Lice treatment

Uses treats head, pubic (crab), and body lice

Warnings For external use only

Do not use

- near eyes
- inside nose, mouth or vagina
- on lice in eyebrows or eyelashes. See a doctor if lice are present in these areas.

Ask a doctor before use if you are allergic to ragweed. May cause breathing difficulty or an asthmatic attack.

When using this product

- keep eyes tightly closed and protect eyes with a washcloth or towel
- if product gets in eyes, flush with water right away
- scalp itching or redness may occur

Stop use and ask a doctor if

- breathing difficulty occurs
- eye irritation occurs
- skin or scalp irritation continues or infection occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control center right away.

Directions

- Important: Read warnings before use. Read leaflet inside carton for complete directions before use. Adults and children 2 years and over: Inspect
 - check each household member with a magnifying glass in bright light for lice/nits (eggs)
 - look for tiny nits near scalp, beginning at back of neck and behind ears
 - examine small sections of hair at a time
 - unlike dandruff which moves when touched, nits stick to the hair
 - if either lice or nits are found, treat with this product

11001r



EXP.

8046979 120412





Drug Facts (continued)

Treat

- apply this product thoroughly to dry hair or other affected area. For head lice, first apply behind ears and to back of neck.
- allow this product to remain on hair or other affected area for 10 minutes, but no longer
- wash area thoroughly with warm water and soap or shampoo
- for head lice, towel dry hair and comb out tangles

Remove lice and their eggs (nits)

- use a fine-tooth comb or the special lice/nit comb. Remove any remaining nits by hand (using a throw-away glove).
- hair should remain slightly damp while removing nits
- if hair dries during combing, dampen slightly with water
- for head lice, part hair into sections. Do one section at a time starting on top of head. Longer hair may take 1 to 2 hours.
- lift a 1 to 2 inch wide strand of hair. Place comb as close to scalp as possible and comb with a firm, even motion away from scalp.
- pin back each strand of hair after combing
- clean comb often. Wipe nits away with tissue and discard in a plastic bag. Seal bag and discard to prevent lice from coming back.
- after combing, thoroughly recheck for lice/nits. Repeat combing if necessary.
- check daily for any lice/nits that you missed
- a second treatment with this product must be done in 7 to 10 days to kill any newly hatched lice
- if infestation continues, see a doctor for other treatments

Children under 2 years: ask a doctor

Other information

- store at 20-25°C (68-77°F). Avoid excessive heat.
- keep carton for important product information
- see leaflet inside carton for additional information

mportant Read w

- Read warnings before use.
- Read leaflet inside carton for complete directions before use.
- Keep carton for important product information.

Throw-away Gloves Made in China

Inactive ingredients butylated hydroxytoluene, carboxymethylcellulose sodium, dimethicone, fragrance, hydroxyethylcellulose, methylchloroisothiazolinone.

methylisothiazolinone, petroleum distillates, water Questions? 1-866-252-5327 Reckitt Bencklser You may also report side effects to this phone number. LiceMD® Comb Dist. by: Reckitt Benckiser Parsippany, NJ 07054-0224 Directions © 2012 RB For Head Lice Please visit our web site www.LiceMD.com Please read the leaflet for complete directions before use. **Limited consumer guarantee: Use AFTER LiceMD treatment gel and shampooing steps. If you are not satisfied with LiceMD®, comb out the dead lice, eggs, and nits with the enclosed LiceMD comb. Please read the entire leaflet for complete directions. This step is very important. Reckitt Benckiser LLC will refund your purchase price. start at the top of the head, comb one section at a time and it is important to get the teeth of the comb very close to the scalp. Combing can take over an hour. Send original UPC code from carton with if hair dries before combing, dampen slightly with warm water price paid and reason for dissatisfaction to: ■ soak all combs, bobby pins, and hair clips with hot water [above 54°C (130°F)] Reckitt Benckiser LLC after combing Attn: Consumer Relations check daily for any lice/nits that you have missed P.O. Box 224 Parsippany, NJ 07054-0224 Throw-Away Gloves ■ 100% nitrile powder-free Limit one per household latex-free non-sterile single-use

LICEMD TREATMENT

pyrethrum extract and piperonyl butoxide gel

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:63824-900
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Pyrethrum Extract (Pyrethrum Extract)	Pyrethrum Extract	0.33 g in 100 mL	
Piperonyl Butoxide (Piperonyl Butoxide)	Pipero nyl Buto xide	4 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
butylated hydroxytoluene			
carboxymethylcellulose sodium			
dimethicone			
methylchloroisothiazolinone			
methylisothiazolinone			
water			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:63824-900-64	1 in 1 CARTON		
1	118 mL in 1 BOTTLE, DISPENSING		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part358G	11/0 1/20 12	

Labeler - Reckitt Benckiser LLC (094405024)

Revised: 1/2013 Reckitt Benckiser LLC