

LICE MD COMPLETE- pyrethrum extract and piperonyl butoxide
Reckitt Benckiser 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.

Lice MD[®]
Complete Kit

LiceMD[®] Treatment Gel

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
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

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, methylchloroisoithiazolinone, methylisothiazolinone, petroleum distillates, water

Questions?

1-866-252-5327. You may also report side effects to this phone number.

LiceMD Shampoo (Non-medicated)

Important: Read leaflet inside carton for complete directions before use.

For external use only. Avoid contact with eyes. If contact occurs, rinse thoroughly with water. Keep out of reach of children.

Directions

- for use after treatment with LiceMD[®] Treatment Gel

- rinse hair with warm water and apply LiceMD Shampoo (Non-Medicated)
- thoroughly massage shampoo into the scalp and work into a lather
- be sure to shampoo behind ears and on back of neck too
- rinse thoroughly with warm water
- repeat if necessary to remove all traces of LiceMD[®] Treatment Gel
- towel dry hair and comb out tangles with a wide-tooth comb
- This shampoo does not kill lice or their eggs (nits). Use this shampoo only after using the LiceMD[®] Treatment Gel contained in this carton or another similar lice treatment product.

Ingredients

water, sodium laureth sulfate, sodium chloride, cocamidopropyl betaine, cocamide DEA, lauramide DEA, fragrance, diethanolamine, glycerin, polysorbate-20, citric acid, tetrasodium EDTA, methylchloroisothiazolinone, methylisothiazolinone, propylene glycol, dimethicone

Questions?

1-866-252-5327

store at 20-25°C (68-77°F).

LiceMD Shampoo Made in Canada
Throw-away Gloves Made in China

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

PRINCIPAL DISPLAY PANEL - Kit Carton

SATISFACTION GUARANTEED

100%

GUARANTEE

OR YOUR MONEY BACK**

LiceMD[®]

COMPLETE KIT

NDC 63824-916-00

LiceMD[®]

COMPLETE KIT

with 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

WASH - clean hair

KIT CONTAINS:

1 Lice Killing Gel 4 FL OZ (118mL)

1 Comb

1 Shampoo (Non medicated) 4 FL OZ (118mL)

2 Pairs of gloves

* The LiceMD[®] comb eliminated 100% lice eggs in laboratory testing

NDC 63824-916-00



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- 2 Pairs of gloves

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**Limited consumer guarantee:

If you are not satisfied with LiceMD[®], Reckitt Benckiser LLC will refund your purchase price.

Send original UPC code from carton with price paid and reason for dissatisfaction to:

Reckitt Benckiser LLC
Attn: Consumer Relations
P.O. Box 224
Parsippany, NJ 07054-0224

Limit one per household



LiceMD[®]

COMPLETE KIT

KILLS LICE & ELIMINATES 100% of THEIR EGGS*

COMPLETE KIT

LiceMD[®]



LiceMD® Treatment Gel

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When using this product

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- scalp itching or redness may occur

Stop use and ask a doctor if

- breathing difficulty occurs ■ eye irritation occurs
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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:**

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- 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
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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 ▶

Drug Facts (continued)

- 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, carbonylmethylcellulose 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 Shampoo (Non-Medicated)

Important: Read leaflet inside carton for complete directions before use.

For external use only. Avoid contact with eyes. If contact occurs, rinse thoroughly with water. Keep out of reach of children.

Directions

- for use after treatment with LiceMD® Treatment Gel
- rinse hair with warm water and apply LiceMD Shampoo (Non-Medicated)
- thoroughly massage shampoo into the scalp and work into a lather
- be sure to shampoo behind ears and on back of neck too
- rinse thoroughly with warm water
- repeat if necessary to remove all traces of LiceMD® Treatment Gel
- towel dry hair and comb out tangles with a wide-tooth comb
- This shampoo does not kill lice or their eggs (nits). Use this shampoo only after using the LiceMD® Treatment Gel contained in this carton or another similar lice treatment product. ▶

Ingredients water, sodium laureth sulfate, citric acid, cocamidopropyl betaine, sodium chloride, PEG-150 pentaerythrityl tetraacetate, fragrance, PPG-2 hydroxyethyl cocamide, polysorbate 20, tetrasodium EDTA, magnesium nitrate, propylene glycol, sodium hydroxide, methylchloroisothiazolinone, magnesium chloride, dimethicone, methylisothiazolinone, trisodium EDTA, sodium ferrocyanide

Questions? 1-866-252-5327

store at 20-25°C (68-77°F).

LiceMD® Comb

Uses removes lice and nits (eggs)

Directions

For Head Lice

- make sure you are in a well-lit area before beginning the comb out process
- after shampooing, part hair into sections about ½ inch thick and 1 to 2 inches wide
- comb one section at a time starting on the top of the head
- combing may take over one hour. Longer hair may take up to 2 hours or more.
- lift a ½ inch thick and 1 to 2 inch wide section of hair at a time
- place the LiceMD® comb as close to scalp as possible
- comb from the roots to the tip of the hair with a firm, even motion away from scalp. Make sure that all of the hair goes through the teeth of the comb. Nits are found on the hair shaft near the roots of the hair, so it is important to get the teeth of the LiceMD® comb very close to the scalp.
- pin back each section of hair that you just finished combing using a bobby pin or hair clip
- take another small section of hair and repeat the combing process until all sections are complete
- hair should remain slightly damp while removing nits. If hair dries during combing, dampen slightly with warm water.
- after the comb-out process is complete, remove all bobby pins and hair clips and rinse with warm water
- thoroughly recheck for lice/nits
- repeat combing if necessary
- remove any remaining nits by hand (using a throw-away glove)
- check daily for any lice/nits that you have missed
- remember to clean the LiceMD® comb often while combing. Wipe nits off of LiceMD® comb with a tissue or dry paper towel and discard in a plastic bag.
- soak all combs, bobby pins and hair clips in hot water [above 54°C (130°F)] for at least 10 minutes when combing is complete. Seal bag and throw away to prevent lice from coming back.

Throw-Away Gloves

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

Important

- Read warnings before use.
- Read leaflet inside carton for complete directions before use.
- Keep carton for important product information.
- Lice treatment is for adults and children 2 years and older.
- See leaflet inside carton for directions on how to use LiceMD® Treatment Gel to treat pubic (crab) lice and body lice.

LiceMD Shampoo Made in Canada
 Throw-away Gloves Made in China



Dist. by: Reckitt Benckiser
 Parsippany, NJ 07054-0224
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Please visit our web site www.LiceMD.com

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Lot

EXP.

LICE MD COMPLETE

pyrethrum extract and piperonyl butoxide kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63824-916

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-916-00	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, DISPENSING	118 mL
Part 2	1 BOTTLE	118 mL

Part 1 of 2

LICEMD TREATMENT

pyrethrum extract and piperonyl butoxide gel

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Pyrethrum Extract (UNII: ZUM06L90GV) (Pyrethrum Extract - UNII:ZUM06L90GV)	Pyrethrum Extract	0.33 g in 100 mL
Piperonyl Butoxide (UNII: LWK91TU9AH) (Piperonyl Butoxide - UNII:LWK91TU9AH)	Piperonyl Butoxide	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
carboxymethylcellulose sodium (UNII: K679OBS311)	
dimethicone (UNII: 92RU3N3Y1O)	
methylchloroisothiazolinone (UNII: DEL7T5QRPN)	
methylisothiazolinone (UNII: 229D0E1QFA)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	11/01/2012	

Part 2 of 2

LICEMD (NON-MEDICATED)

shampoos (non-coloring) shampoo

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	water (UNII: 059QF0KO0R)	
INGR	sodium laureth-3 sulfate (UNII: BPV390UAP0)	
INGR	citric acid monohydrate (UNII: 2968PHW8QP)	
INGR	cocamidopropyl betaine (UNII: 5OCF3O11KX)	
INGR	sodium chloride (UNII: 451W47IQ8X)	
INGR	PEG-150 pentaerythrityl tetrastearate (UNII: 8L4OOQ76AM)	
INGR	PPG-2 hydroxyethyl cocamide (UNII: 34N07GUJ3X)	
INGR	polysorbate 20 (UNII: 7T1F30V5YH)	
INGR	edetate sodium (UNII: MPIJ8420LU)	
INGR	magnesium nitrate (UNII: 77CBG3UN78)	
INGR	propylene glycol (UNII: 6DC9Q167V3)	
INGR	sodium hydroxide (UNII: 55X04QC32I)	
INGR	methylchloroisothiazolinone (UNII: DEL7T5QRPN)	
INGR	magnesium chloride (UNII: 02F3473H9O)	
INGR	dimethicone (UNII: 92RU3N3Y1O)	
INGR	methylisothiazolinone (UNII: 229D0E1QFA)	
INGR	edetate trisodium (UNII: 420IP921MB)	
INGR	sodium ferrocyanide (UNII: 5HT6X21AID)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		11/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358G	11/01/2012	

Labeler - Reckitt Benckiser LLC (094405024)