

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-043**

**FINAL PRINTED LABELING**

**MAXIMUM STRENGTH**



**MOUSSE**

Easy To Apply  
Non-drip Formula

Pleasant Scent

KILLS LICE



KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

Distributed by CONSUMER HEALTHCARE GROUP/Pfizer Inc., New York, NY 10017

### **Drug Facts**

**Active ingredients**  
(calculated without propellant)  
Piperonyl butoxide (4%), Pyrethrin extract\*  
(equivalent to 0.33% pyrethrins)

**Purpose** lice treatment

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

#### **Warnings**

- For external use only
- Flammable: Keep away from fire or flame

**Do not use near the eyes**

Ask a doctor before use if you have  
an allergy to ragweed

**When using this product**

- keep out of eyes when rinsing hair
- close eyes tightly and do not open eyes until product is rinsed out
- protect eyes with washcloth, towel or other suitable method
- If product gets into the eyes, immediately flush with water
- do not use inside the nose, mouth, or vagina. Irritation may occur.
- do not inhale; use in a well ventilated area
- do not puncture or incinerate. Contents under pressure.

**Stop use and ask a doctor if**

- skin irritation or infection is present or develops
- inflammation of eyebrows or eyelashes occurs

**Keep out of reach of children.**

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

NET WT. 5.5 OZ (156 g)

### **Drug Facts (continued)**

#### **Directions**

- Important: Read warnings before using
- shake well before using
- holding the can upside down, apply RID Mousse to dry hair or other affected area. Massage until all the hair is thoroughly wet with product. For best results against head lice, see complete Directions in the Consumer Information Insert.
- allow product to remain on the hair for 10 minutes but no longer
- wash area thoroughly with warm water and soap or shampoo
- a fine-toothed comb or a special lice/nit removing comb may be used to help remove dead lice or their eggs (nits) from hair
- a second treatment must be done in 7 to 10 days to kill any newly hatched lice

#### **Other Information**

- store at 20°-25°C (68°-77°F)
- do not store at temperature above 43°C (110°F)
- keep in a cool place out of the sun

**Inactive ingredients** cetyl alcohol, isobutane, PEG-20 stearate, propane, propylene glycol, purified water, quaternium-52, SD Alcohol 3-C (26.5% v/v)

For Questions call 1-800-RID LICE  
(1-800-743-5423)

Visit us at <http://www.lice-rid.com>

\*50% extract (not USP)

U.S. Pat. 6,783,202

SN 25120001P

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ENLARGED FOR PROOFREADING

match  
desk

128 CODE



# MOUSSE

## Drug Facts

**Active ingredients (calculated without propellant) Purpose**  
Piperonyl butoxide (4%) For treatment  
Pyrethrum extract\* (equivalent to 0.53% Pyrethrins) For treatment

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

### Warnings

- For external use only
- Flammable. Keep away from fire or flame.

**Do not use near the eyes.**

**Avoid a doctor before use if you have an allergy to ragweed.**

**When using this product:**

- keep out of eyes when rinsing hair
- close eyes tightly and do not open eyes until product is rinsed out
- protect eyes with washcloth, towel or other suitable method
- if product gets into the eyes, immediately flush with water
- do not use inside the nose, mouth, or vagina. Irritation may occur.
- do not inhale; use in a well ventilated area.
- do not puncture or incinerate. Contents under pressure.

**Stop use and seek a doctor if:**

- skin irritation or infection is present or develops
- irritation of eyebrows or eyelashes 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 using
- shake well before using
- holding the can upside down, apply RID® Mousse to dry hair or other affected area. Massage until all the hair is thoroughly wet with product. For best results against head lice, see complete Directions in the Consumer Information Insert.
- allow product to remain on the hair for 10 minutes but no longer
- wash area thoroughly with warm water and soap or shampoo
- a fine-toothed comb or a special louse-removing comb may be used to help remove dead lice or their eggs (nits) from hair
- a second treatment must be done in 7 to 10 days to kill any newly hatched lice

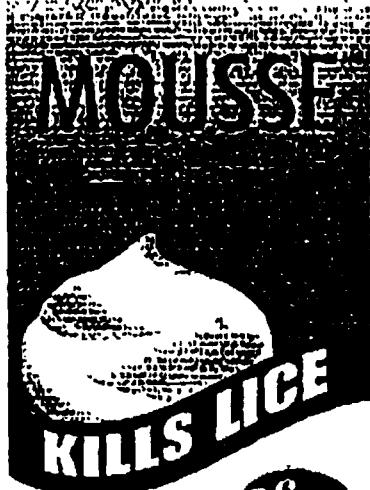
### Other Information

- store at 20°-25°C (68°-77°F)
- do not store at temperatures above 45°C (110°F)
- keep in a cool place out of the sun

**Inactive Ingredients** octenyl alcohol, isobutane, PEG-20 ethoxate, propane, propylene glycol, purified water, quaternium-52, SD Alcohol 3-G (25.5% w/v).

Questions? call 1-800-RID LICE  
(1-800-743-5423)

**MAXIMUM STRENGTH**



Distributed By  
CONSUMER HEALTH CARE GROUP,  
PFIZER INC., NEW YORK, NY 10017

U.S. Pat. 5,783,202 SM 4012000SP  
\*50% extract (not USP)

EXP

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ENLARGED FOR PROOFREADING

## CONSUMER INFORMATION INSERT TREATING LICE INFESTATION WITH

128 CODE



### MOUSSE

pyrethrum extract\* (equivalent to 0.33% pyrethrins)  
and piperonyl butoxide (4%)  
cosmotol foam

PEDICUCIDE (LICE TREATMENT)

KILLS LICE

This insert will tell you about human lice and how to treat infestation effectively with RID® Mousse. Lice are parasitic insects the size of a sesame seed. They can infest people at all social levels; no one is immune. Lice are easily transmitted from person to person by shared personal articles such as hats, hair ribbons, combs, towels and bedding, and by physical contact. Infestation of lice can be easily treated today. This package of RID® Mousse, with its special patented comb, is a complete product designed to treat and remove lice and their eggs rapidly and effectively. (The principal active ingredient of RID® Mousse is pyrethrum extract, derived from a species of chrysanthemum flower.)

### THERE ARE 3 TYPES OF LICE WHICH INFEST HUMANS

Head Lice:

- head lice live on the scalp and lay small white eggs (nits) on the hair shaft close to the scalp
- the nits are most easily found on the nape of the neck or behind the ears
- all personal headgear, scarfs, coats, and bed linens should be disinfected by machine washing in hot water and drying, using the hot cycle of a dryer for at least 20 minutes
- personal articles of clothing or bedding that cannot be washed may be dry-cleaned, sealed in a plastic bag for a period of about 2 weeks, or sprayed with a product specifically designed for this purpose
- personal combs and brushes may be disinfected by soaking in hot water above 54°C (130°F) for 5 to 10 minutes
- thorough vacuuming of rooms inhabited by affected people is recommended

Pubic (Crab) Lice:

- pubic lice may be transmitted by sexual contact; therefore, sexual partners should be treated simultaneously to avoid reinfection
- the lice are very small and look almost like brown or grey dots on the skin
- pubic lice usually cause intense itching and lay small white eggs (nits) on the hair shaft generally close to the skin surface
- in hairy individuals, pubic lice may be present on the short hairs of the groin, thighs and trunk, underarms, and occasionally on the beard and mustache
- underwear should be disinfected by machine washing in hot water, then drying, using the hot cycle for at least 20 minutes

Body Lice:

- body lice and their eggs are generally found in the seams of clothing, particularly in the waistline and armpit area
- they move to the skin to feed, then return to the seams of the clothing where they lay their eggs
- clothing worn and not laundered before treatment should be disinfected by the same procedure as described for head lice, except that sealing clothing in a plastic bag is not recommended for body lice because the nits (eggs) from these lice can remain dormant for a period of up to 30 days.

### TREATMENT OF LICE INFESTATION

#### DIRECTIONS:

##### IMPORTANT: READ WARNINGS BEFORE USING.

- Shake well before using.
- Holding can upside down, apply RID® Mousse to dry hair or other affected area. Massage until all the hair is thoroughly wet with product. For head lice, the mousse can best be applied by parting the hair and placing a line of foam along the part and working it outwards into the hair. Or, the mousse can be applied with the nozzle placed under the layers of hair, then massaged into the hair across the scalp from that point. Be sure to completely moisten all the hair with the product.

\*30% extract (not USP)

- Allow the product to remain on the area for 10 minutes but no longer. Ten minutes is the time needed for the product to effectively treat lice. Leaving it on longer has not been demonstrated to increase its effectiveness.
- Wash area thoroughly with warm water and soap or shampoo.
- A fine-toothed comb or a special lice/uit removing comb may be used to help remove dead lice or their eggs (nits) from hair. A patented RID® nit (egg) removal comb is included in this package.

### COMB HAIR PROPERLY

You must thoroughly comb out the nits in order to prevent reinfection. This can be time consuming, but it is necessary. To effectively remove nits with the provided RID® nit comb, follow these six easy steps below:

1. While hair is still damp, comb hair with your regular comb to remove snarls and tangles. Part hair into four sections, and pick one section at a time to work on.
2. Start at the top in the section of the hair you have picked. With one hand, tilt a small amount of hair—about one-half inch wide.
3. Take the provided RID® comb, and comb with a firm even motion away from the scalp/skin to the end of the hair.
4. Make sure the teeth of the comb are as deep into the hair as they can go and touching the scalp/skin.
5. Wipe eggs (nits) completely from comb with a tissue. Toss the tissue in a sealable bag to avoid reinfection. Using bobby pins or clips, pin back each tuft of hair after you have combed out the nits.
6. Repeat steps 2 through 5 for the remaining sections of hair. If hair dries during combing, dampen slightly with water. After you have combed the entire head/affected area, rinse thoroughly with warm water.

■ A second treatment must be done in 7 to 10 days to kill any newly hatched lice.

### PREVENT REINFESTATION

Lice can survive for up to a day off the human scalp, on personal items, stuffed animals, household surfaces, clothing and bed linens. They may also spread from person to person. Without killing these lice, reinfection can occur. Here are steps you can take to prevent reinfection:

- Family members and other close contacts should also be inspected for lice. If infestation occurs, treatment should be initiated as described above.
- Soak all combs and brushes in hot water—at least 54°C (130°F) for 10 minutes. Always inspect and rinse thoroughly before using.
- Wash clothing and linens in hot water and then place in a hot dryer for 20 minutes.
- For items that cannot be washed or dry-cleaned, place in a tightly sealed plastic bag for 14 days, then open outdoors and shake vigorously.
- Personal articles of clothing or bedding that cannot be washed may be dry-cleaned, sealed in a plastic bag for a period of about 2 weeks, or sprayed with a product specifically designed for this purpose.
- Vacuum everywhere. Vacuum all carpets, mattresses, upholstered furniture and car seats that may have been used by infested household members.
- Tell children not to use any borrowed combs or brushes, or to wear anyone else's clothes.

### WARNINGS:

- For external use only.
- Flammable. Keep away from fire or flame.
- Do not use near the eyes.
- Ask a doctor before use if you have an allergy to ragweed.
- When using this product:
  - keep out of eyes when rinsing hair
  - close eyes tightly and do not open eyes until product is rinsed out
  - protect eyes with washcloth, towel or other suitable method
  - if product gets into the eyes, immediately flush with water
  - do not use inside the nose, mouth, or vagina. Irritation may occur.
  - do not inhale; use in a well ventilated area
  - do not puncture or incinerate. Contains under pressure
- Stop use and see a doctor if:
  - skin irritation or infection is present or develops
  - infestation of eyebrows or eyelashes occurs
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

### OTHER INFORMATION

- Store at 20°-25°C (68°-77°F)
- Do not store at temperature above 43°C (110°F)
- Keep in a cool place out of the sun

QUESTIONS? Call 1-800-RID-LICE (1-800-743-5423)

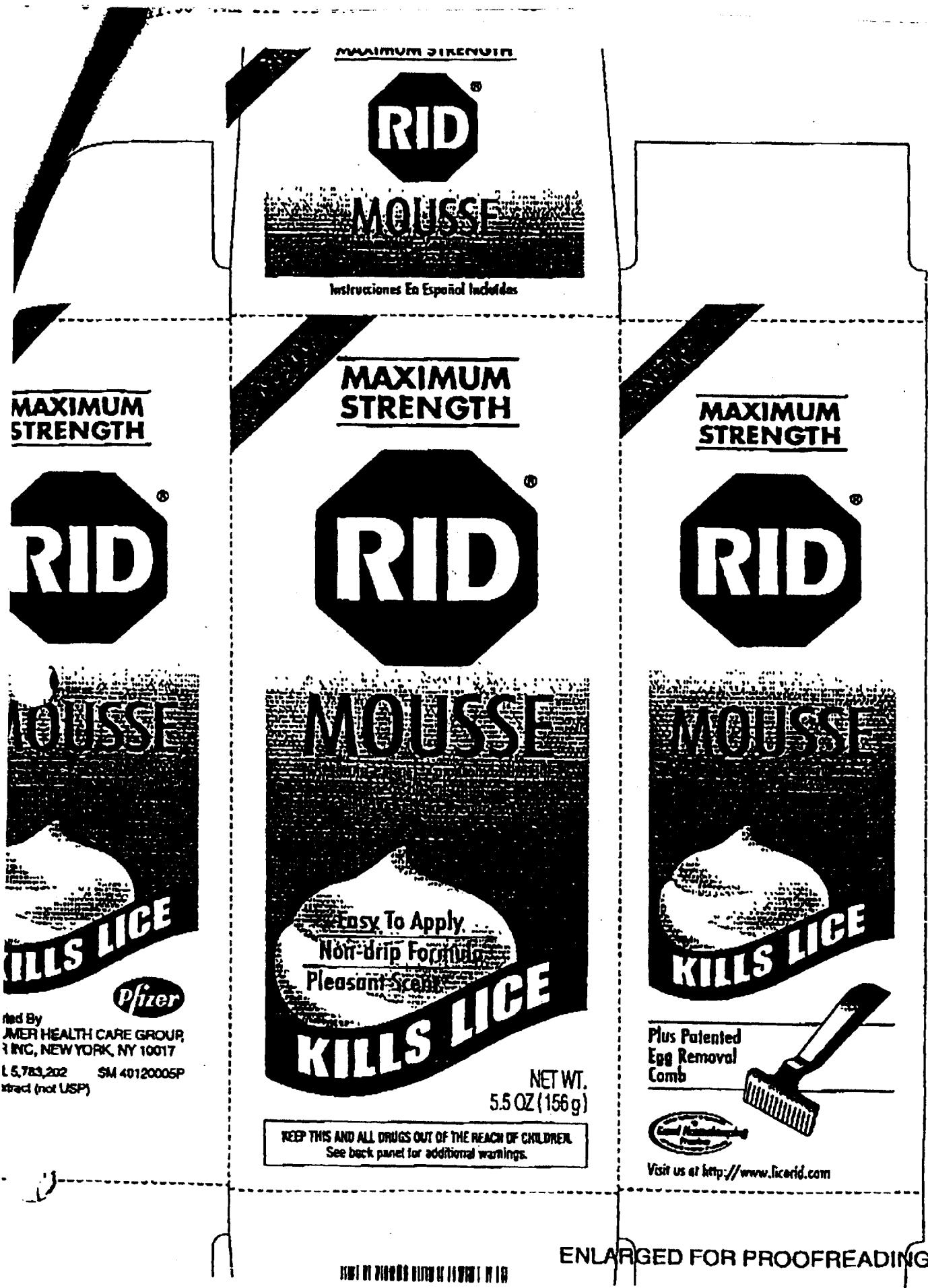


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CONSUMER HEALTH CARE GROUP, PFIZER INC., NEW YORK, N.Y. 10017

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ENGLISH SIDE ONE

Consumer Health Care Group 11 East 52nd Street New York, New York 10017 Telephone 212-632-6160 FAX 212-632-6167	Color Panels	Approved	Printed (or Type) By
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