MATA PIOJOS LICE- piperonyl butoxide, pyrethrum extract shampoo Grandall Distributing Company 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.

Mata Piojos Lice Shampoo

Drug Facts

Active ingredients

Piperonyl butoxide 4%

Pyrethrum extract (equivalent to 0.33% pyrethrins)

Purpose

Lice treatment

Uses

treat 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 regweed. 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
- 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 thoroughly to dry hair or other affected area. For head lice, first apply behind ears and to back of nick.
- allow product to remain for 10 minutes, but no longer
- use warm water to form a lather, shampoo, then thoroughly rinse
- for head lice, towel dry hair and comb cut tangles

Remove lice and their eggs (nits)

- I use a fine-tooth or special lice/nit comb. Remove any remaining nits by hand (using a throw-away glove).
- hari 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 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

- do not freeze
- store at controlled room temperature, 20°C to 25°C (68° F to 77° F)
- to report serious side effects due to the use of this product call (515) 276-1586
- see package insert for additional information

Inactive ingredients

ammonium laureth sulfate, fragrance, PEG-25 hydrogenated castor oil, polyquaternium-10, purified water, SD-40 alcohol

Package Labeling:

PIOJOS

LICE SHAMPOO

Drug Facts (continued)

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Hair Length	Recommended Application† for 1 Adult/Child
Short (ear length	Day 1: 1 - 2 oz Day 7-10: 1 - 2 oz
or shorter)	Total: 2 - 4 oz
Medium (shoulder length)	Day 1: 2 - 3 oz Day 7-10: 2 - 3 oz
	Total: 4 - 6 oz
Long (past shoulder	Day 1: 3 - 4 oz Day 7-10: 3 - 4 oz
length)	Total: 6 - 8 oz

†Recommended application dependent upon hair thickness

Largo del cabello	Cantidad recomendada para I adulto/niño		
Corto (hasta la oreja o más corto)	Día 1: 1 - 2 oz Día 7-10: 1 - 2 oz		
	Total: 2 - 4 oz		
Medio (hasta el hombro)	Día 1: 2 - 3 oz Día 7-10: 2 - 3 oz		
	Total: 4 - 6 oz		
Largo (más abajo del hombro)	Día 1: 3 - 4 oz Día 7-10: 3 - 4 oz		
	Total: 6 - 8 oz		

Important: keep this outer carton for future reference.

Distributed by: Grandall Dist. Co., Inc. Glendale, CA 91204-2707 1-800-344-2422 www.matapiojo.com



MAT'A 210J0S **LICE SHAMPOO**

Champú Para Eliminar Piojos

INSTRUCCIONES EN ESPAÑOL INCLUIDAS

MATA PIOJOS TRATAMIENTO

- SHAMPOO Y ACONDICIONADOR EN UNO
- ELIMINA PIOJOS Y LADILLAS
- EFECTIVO, RAPIDO Y SEGURO
- ELIMINATES HEAD, BODY AND PUBIC (CRAB) LICE

LICE REMOVAL **COMB INSIDE**



LARGE SIZE

8 fl oz (237 mL)

Drug Facts

Active ingredients

Purpose

Piperonyl butoxide 4% Lice treatment Pyrethrum extract (equivalent to

0.33% pyrethrins) 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
- 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

Drug Facts (continued)

- unlike dandruff which moves when touched, nits stick to the hair
- if either lice or nits are found, treat with this product

- . apply thoroughly to dry hair or other affected area. For head lice, first apply behind ears and to back of neck,
- allow product to remain for 10 minutes, but no longer
- use warm water to form a lather. shampoo, then thoroughly rinse
- for head lice, towel dry hair and comb out tangles

Remove lice and their eggs (nits)

- use a fine-tooth or 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.
- opin 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.
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- a second treatment must be done in 7 to 10 days to kill any newly hatched lice
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- children under 2 years: ask a doctor

This product is not manufactured by Bayer HealthCare, distributor of the product RID®



LOT NO.

EXPIRES

Drug Facts (continued)

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08-253-08v1.0

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MATA PIOJOS® LICE SHAMPOO Champú Para Eliminar Piojos MATA PIOJOS TRATAMIENTO SHAMPOO Y ACONDICIONADOR EN UNO **ELIMINA PIOJOS Y** LADILLAS EFECTIVO, RAPIDO Y SEGURO ELIMINATES HEAD, BODY AND PUBIC (CRAB) LICE MATA LICE REMOVAL **PIOJOS** COMB INSIDE LICE SHAMPOO **LARGE SIZE** 8 fl oz (237 mL)

Important: keep outer carton for complete information.

Drug Facts Active ingredients Purpose Piperonyl butoxide 4%.....Lice treatment Pyrethrum extract (equivalent to 0.33% pyrethrins).....Lice treatment Uses treats head lice, pubic (crab) lice, and body lice. Warnings For external use only. Do not use near eves ● 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.

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behind ears • examine small sections of hair at a time

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> DO NOT PRINT! space reserved for LOT & EXP

MATA PIOJOS LICE

piperonyl butoxide, pyrethrum extract shampoo

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:48201-367 Route of Administration TOPICAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
(PIPERONYL BUTO XIDE	40 mg in 1 mL			
	PYRETHRUM EXTRACT	3.3 mg in 1 mL			

Inactive Ingredients	
Ingredient Name	Strength
PEG-25 HYDRO GENATED CASTOR OIL (UNII: 0ZNO9PJJ9J)	
WATER (UNII: 059QF0KO0R)	

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:48201-367-00	1 in 1 BOX	06/01/2018				
1	237 mL in 1 BOTTLE; Type 0: Not a Combination Product					
Marketing Information						
Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
Marketing Categor		Marketing Start Date 06/01/2018	Marketing End Date			

Labeler - Grandall Distributing Company Inc (044428324)

Revised: 10/2019 Grandall Distributing Company Inc