

PRONTO PLUS LICE KILLING- pyrethrum extract and piperonyl butoxide shampoo
Insight Pharmaceuticals 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.

PRONTO®
PLUS

Lice Killing Shampoo with Extracts

Drug Facts

Active ingredients

Pyrethrum extract (pyrethrins 0.33%) with piperonyl butoxide 4%

Purpose

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 of age and over:**

Inspect

- check each household member with a magnifying glass in bright light for lice and nits
- 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

- shake bottle well
- 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 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.
- 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 and nits. Repeat combing if necessary.
- check daily for any lice and 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 of age:** ask a doctor

Other Information

HEAD LICE: lay small white eggs (nits) on hair shaft close to scalp

- nits are most easily found on back of neck or behind ears
- disinfect hats, hair ribbons, scarves, coats, towels, and bed linens by machine washing in hot water [above 54°C (130°F)], then using hottest dryer cycle for at least 20 minutes
- items that cannot be washed (bedspreads, blankets, pillows, stuffed toys, etc.) should be dry-cleaned or sealed in a plastic bag for 4 weeks, then removed outdoors and shaken out very hard before using again
- items that cannot be washed, dry-cleaned, or stored may be sprayed with a product designed for this purpose
- allow all sprayed articles to dry thoroughly before use
- soak all combs and brushes in hot water [above 54°C (130°F)] for at least 10 minutes
- vacuum all carpets, mattresses, upholstered furniture, and car seats that may have been used by affected people

Keep carton for full drug facts and warnings. Read all warnings and directions before use.

- visit our website at www.insightpharma.com

Inactive Ingredients

cananga odorata flower oil, chamomilla recutita (matricaria) flower extract, fragrance, melaleuca alternifolia (tea tree) leaf oil, PEG-45 palm kernel glycerides, pimpinella anisum (anise) fruit extract, propylene glycol, water, sodium laureth sulfate.

Questions?

call 1-888-542-3546

Distributed by:

INSIGHT Pharmaceuticals Corp.

1170 Wheeler Way

Langhorne, PA 19047-1749

PRINCIPAL DISPLAY PANEL - Kit Carton

PRONTO®

PLUS

Complete Lice Removal System

3-STEP LICE ELIMINATION KIT

1 LICE KILLING SHAMPOO WITH EXTRACTS

Pyrethrum extract (pyrethrins 0.33%) with piperonyl butoxide 4% (Lice treatment)

- ***MAXIMUM STRENGTH LICE KILLING INGREDIENT TO KILL LICE & NITS (their eggs)***
- ***CONTAINS CHAMOMILE, ANISE, YLANG YLANG OIL & TEA TREE OIL***
- ***LEAVES NO CHEMICAL RESIDUE BEHIND***

2 LICE EGG REMOVER GEL AND COMB

- ***GEL MAKES LICE NIT (EGG) REMOVAL EASIER THAN LICE KILLING SHAMPOO ALONE***
- ***INCLUDES NIT REMOVAL COMB***

3 PRONTO® PLUS HOUSEHOLD SPRAY KILLS LICE, TICKS, FLEAS, DUST MITES & BEDBUGS

- ***Kills Adult Lice & Nymphs as They Hatch on Bedding, Garments, Furniture and Other Inanimate Objects***

CAUTION: KEEP OUT OF REACH OF CHILDREN

See Back/Side Panel For Additional Precautions And First Aid

SHAMPOO 2 FL OZ (59 mL), GEL 2 FL OZ (59 mL), COMB, GLOVES, SPRAY 5 OZ (142 g)

PRONTO[®] PLUS

Complete Lice Removal System

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PRONTO[®] PLUS

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Lice Killing Shampoo with Extracts (continued)

Drug Facts (continued)

- check daily for any lice and 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 of age: ask a doctor

Other Information

HEAD LICE: lay small white eggs (nits) on hair shaft close to scalp • nits are most easily found on back of neck or behind ears • disinfest hats, hair ribbons, scarves, coats, towels, and bed linens by machine washing in hot water (above 54°C (130°F)), then using hottest dryer cycle for at least 20 minutes • items that cannot be washed (bedspreads, blankets, pillows, stuffed toys, etc.) should be dry-cleaned or sealed in a plastic bag for 4 weeks, then removed outdoors and shaken out very hard before using again • items that cannot be washed, dry-cleaned, or stored may be sprayed with a product designed for this purpose • allow all sprayed articles to dry thoroughly before use • soak all combs and brushes in hot water (above 54°C (130°F)) for at least 10 minutes • vacuum all carpets, mattresses, upholstered furniture, and car seats that may have been used by affected people
Keep carton for full drug facts and warnings. Read all warnings and directions before use.
• visit our website at www.insightpharma.com

Inactive Ingredients cananga odorata flower oil, chamomile, scutella (matricaria) flower extract, fragrance, melaleuca alba (tea tree) leaf oil, PEG-45 palm kernel glyceride, pim. pinella anisum (anise) fruit extract, propylene glycol, water, sodium lauryl sulfate.

TIPS & TECHNIQUES

- Product usage will vary by hair length. Suggested dosage follows:

Hair Length	Approximate Suggested Dosage	
	Lice Killing Shampoo	Lice Egg Remover Gel
Short (ear length or shorter)	Day 1: 1oz-2oz	Day 1: 1oz
	Day 7: 1oz-2oz	Day 7: 1oz
	Total: 2oz-4oz	Total: 2oz
Medium (shoulder length)	Day 1: 2oz-3oz	Day 1: 2oz
	Day 7: 2oz-3oz	Day 7: 2oz
	Total: 4oz-6oz	Total: 4oz
Long (past shoulders)	Day 1: 3oz-4oz	Day 1: 2oz
	Day 7: 3oz-4oz	Day 7: 2oz
	Total: 6oz-8oz	Total: 4oz

- It's extremely important to comb out ALL lice and nits from the hair. Usually nits are attached to the side of the hair strand closer to the scalp, with a glue-like substance.

Lice Killing Shampoo with Extracts

Drug Facts

Active ingredients Purpose
Pyrethrum extract (pyrethrins 0.33%)
with piperonyl butoxide 4%..... 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 asthma 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 of age and over:

Treatment
• check each household member with a magnifying glass in bright light for lice and nits • 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 other lice or nits are found, treat with this product

Treat
• shake bottle well • 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 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. • 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 check for lice and nits. Repeat combing if necessary.

Lice Egg Remover Gel and Comb

Product Facts

Uses to remove head lice and nits (their eggs)

Warnings

For external use only. Avoid contact with the eyes.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- use after shampooing with a lice killing shampoo
- towel dry hair
- apply lice egg remover gel until all the hair and scalp is thoroughly wet with product
- make sure product covers the area behind the ears and at the nape of the neck where there are more likely to be nits
- part hair into sections and clip back
- use the enclosed special-toothed comb to comb out dead lice and nits
- comb out one section at a time
- it is extremely important to comb out dead lice and nits
- if hair begins to dry, reapply additional product
- when you finish combing, rinse hair thoroughly with warm water

Other Information

- Pronto Plus Lice Egg Remover Gel does not kill lice and nits
- pesticide free
- keep caution for full information and warnings. Read all warnings and directions before use.
- visit our website at www.insightpharma.com

Ingredients: purified water, propylene glycol, glycerin, polyquaternium-10, diazolidinylurea, hydroxyethylcellulose, sodium citrate dihydrate, citric acid, methylparaben, propylparaben, disodium EDTA

Questions? call 1-888-542-3648

Distributed by:
INSIGHT Pharmaceuticals Corp.
1170 Wheeler Way
Langhorne, PA 19047-1749

Pronto® Plus Household Spray Kills Lice, Ticks, Fleas, Dust Mites & Bedbugs

Active ingredients:

3-phenoxybenzyl (1RS,3RS,1RS,3SR)-2,2-dimethyl-3-(2-methylprop-1-ynyl)pyrrolidinecarboxylate.....0.4%
N-Octyl bicycloheptane dicarboximide.....1.6%
Other ingredients.....98.0%
100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION

For indoor use in the Home and Non-Food Areas of Restaurants, Schools, Nursing Homes, Warehouses, Offices, Apartments, Hotels, Motels, Kennels, and Hospitals. Not for use on Humans or Animals.

Directions For Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: In hospitals and nursing homes, remove patients before treatment. Ventilate room for two hours before returning patients. This product is not for use on humans. If lice infestation should occur on humans, use a product labeled for use on humans. Do not use in commercial food/feed processing, preparation, food/feed storage or serving areas. In the home, all food/feed processing surfaces and utensils should be covered during treatment, or thoroughly washed before use. Exposed food/feed should be covered or removed. Remove pets, birds and/or cover fish aquariums before spraying. SHAKE WELL BEFORE EACH USE.

APPLICATION: Spray in inconspicuous areas to test for possible staining or discoloration. Evaluate test area after drying. Hold container upright with nozzle aimed away from you. Depress valve and spray from a distance of 8 to 10 inches. Spray each square foot for 5 seconds or until damp. Most effective results are achieved when used as part of a treatment protocol that includes physical, environmental and other chemical pest control measures. Vacate room after treatment and ventilate before reoccupying. Do not allow children or pets to contact treated areas until surfaces are dry. Allow sprayed articles and surfaces to dry thoroughly before using or replacing bedding.

TO KILL LICE: Spray only those garments, parts of bedding, including mattresses and furniture that cannot be either laundered or dry-cleaned.

TO KILL TICKS AND FLEAS: Spray around beds, furniture and pet's habitat. Spray pet sleeping quarters, bedding, floor and floor covering where pets are kept. Use only a recommended pet spray on pets.

TO KILL DUST MITES: Thoroughly vacuum entire room concentrating on areas where mites congregate: such as mattresses, box springs, headboards, walls, floors, carpets, and baseboards. Then spray surfaces until damp.

TO KILL BEDBUGS and BEDBUG EGGS: Apply as a spot treatment to cracks and crevices on and around baseboards, furniture, door and window frames, wallwork and walls. Apply as a surface spray to carpet, mattresses, box springs, walls, furniture, bedding, floor and floor coverings, rugs, garments, luggage, closets, drapes and other window appointments. Thoroughly clean and air-out mattresses and box springs. Then treat areas that may harbor bedbugs or their eggs, such as tufts, folds, and seams. When treating for bedbug eggs, spray each square foot for 13 seconds or until damp.

Pronto® Plus Household Spray Kills Lice, Ticks, Fleas, Dust Mites & Bedbugs

Storage and Disposal

Do not contain in water, food, or feed by storage or disposal. PESTICIDE STORAGE: Store in a cool dry area. Always store pesticides in the original container. Store away from food and pet food.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Do not puncture or incinerate! Nonrefillable container. Do not reuse or refill this container. If empty, place in trash or offer for recycling if available. If partly filled, call your local solid waste agency for disposal instructions.

Precautionary Statements

Hazards to Humans and Domestic Animals
CAUTION: Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

Physical or Chemical Hazards

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. Do not apply this product around electrical equipment due to the possibility of shock hazard.

First Aid

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.

IF SWALLOWED: Immediately call a Poison Control Center or doctor. Do not induce vomiting unless told to do so by a Poison Control Center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment. For information regarding medical emergencies or pesticide incidents, call 1-888-542-3648.

EPA Reg. No. 1021-1767-75406 EPA Est. No. 5693-MA-1

THE PRONTO PLUS SOLUTION TO LICE ELIMINATION

A 3-step process to help eliminate lice from your home and to help prevent reinfestation. With the Pronto Plus Complete Lice Removal System, lice and nits are eliminated in just 3 steps.

1 Kill Lice with Pronto Plus Lice Killing Shampoo with Extracts

Apply Pronto Plus Lice Killing Shampoo with Extracts according to directions.

Reapply in 7-10 days to help prevent reinfestation of newly hatched lice.

2 Comb Out Lice & Nits

After shampooing, apply Pronto Plus Lice Egg Remover Gel to damp hair.

Completely comb out lice and nits with the comb included.

3 Clean Home

Use Pronto Plus Household Spray Kill's Lice, Ticks, Fleas, Dust Mites & Bedbugs on non-washable items to kill lice and nymphs.

IMPORTANT: Read detailed instructions inside before starting. Save information for future use.

6 121 63736 34021 3



PRONTO PLUS LICE KILLING

pyrethrum extract and piperonyl butoxide shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-210
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Pyrethrum Extract (UNII: ZUM06L90GV) (Pyrethrum Extract - UNII:ZUM06L90GV)	Pyrethrum Extract	0.0033 mL in 1 mL
Piperonyl Butoxide (UNII: LWK91TU9AH) (Piperonyl Butoxide - UNII:LWK91TU9AH)	Piperonyl Butoxide	0.04 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Cananga Oil (UNII: 8YOY78GNNX)	
Chamomile (UNII: FGL3685T2X)	
Tea Tree Oil (UNII: VIF565UC2G)	
Pimpinella Anisum (UNII: HO63CL229O)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sodium Laureth Sulfate (UNII: BPV390UAP0)	

Product Characteristics

Color	WHITE (Clear)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-210-12	12 in 1 CASE		
1		1 in 1 BOX		
1		59 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part358G	12/01/2010	

