

**NIX FAMILY PACK LICE KILLING CREME RINSE KIT- permethrin**  
**Geodis Logistics LLC**

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**Nix FAMILY PACK Lice Killing Creme Rinse Kit**

***Drug Facts***

***Active ingredient (in each fluid ounce)***

Permethrin 280 mg (1%)

***Purpose***

Lice treatment

***Uses***

treats head lice

***Warnings***

**For external use only**

**Do not use**

- on children under 2 months of age
- near the eyes
- inside the nose, ear, mouth, or vagina
- on lice in eyebrows or eyelashes.  
See your doctor.

**Ask a doctor before use if you are**

allergic to ragweed. May cause breathing difficulty or an asthmatic episode.

**When using this product**

- keep eyes tightly closed and protect eyes with a washcloth or towel
- if product gets into the eyes, immediately flush with large amounts of water
- 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

**If pregnant or breast-feeding,**

ask a health professional before use.

## **Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

## ***Directions***

### **Important: Read warnings before use**

- **Adults and children 2 months old and older**

### **Inspect**

- all household members should be checked by another person for lice and/or nits (eggs)
- use a magnifying glass in bright light to help you see the lice and/or nits (eggs)
- use a tool, such as a comb or two unsharpened pencils to lift and part the hair
- look for tiny nits near scalp, beginning at the back of the neck and behind the ears
- small sections of hair (1-2 inches wide) should be examined at a time
- unlike dandruff, nits stick to the hair. Dandruff should move when lightly touched,
- if either lice or nits (or eggs) are found, treat with Nix<sup>®</sup> Creme Rinse

### **Treat**

- wash hair with a shampoo without conditioner. Do not use a shampoo that contains a conditioner or a conditioner alone since this may decrease the activity of Nix<sup>®</sup>. Rinse with water.
- towel dry hair so it is damp but not wet
- shake the bottle of Nix<sup>®</sup> well
- completely saturate the hair and scalp with Nix<sup>®</sup>. Begin to apply Nix<sup>®</sup> behind the ears and at the back of the neck.
- keep Nix<sup>®</sup> out of the eyes. Protect the eyes with a washcloth or towel.
- leave Nix<sup>®</sup> on the hair for 10 minutes, but no longer
- rinse with warm water
- towel dry hair and comb out tangles
- if live lice are seen seven days or more after the first treatment, a second treatment should be given

### **Remove Lice/Nits**

- remove nits by combing the hair with the special small tooth comb provided. Remaining nits may be removed by hand (using a throw-away glove), or cutting the nits out.
- use the nit comb provided and make sure the hair remains slightly damp while removing nits
- if the hair dries during combing, dampen it slightly with water
- part the hair into 4 sections. Work on one section at a time. Longer hair may take more time (1-2 hours).
- start at the top of the head on the section you have picked
- with one hand, lift a 1-2 inch wide strand of hair. Get the teeth of the comb as close to the scalp as possible and comb with a firm, even motion away from the scalp to the end of the hair.
- use clips to pin back each strand of hair after you have combed out the nits

- clean the comb completely as you go. Wipe the nits from the comb with a tissue and throw away the tissue in a sealed plastic bag to prevent the lice from coming back.
- after combing, recheck the entire head for nits and repeat combing if necessary
- check the affected head daily to remove any nits that you might have missed

### ***Other information***

- read all the directions in the Consumer Information Insert and warnings before use. Keep the carton. It contains important information.
- store at 20° to 25°C (68° to 77°F)

### ***Inactive ingredients***

canada balsam, cetyl alcohol, citric acid, FD&C yellow no. 6, hydrolyzed animal protein, hydroxyethylcellulose, isopropyl alcohol, methylparaben, polyoxyethylene 10 cetyl ether, propylene glycol, propylparaben, stearylalkonium chloride, water

### ***Questions or comments?***

call **1-888- LICE (1-888-542-3546)**.

Monday to Friday, 9 AM - 5 PM EST

**Package Labeling: 63471-3010-0**

# Nix

Permethrin 1%

Lice Treatment Creme Rinse

## THE FACTS OF LICE

Please read all information before using Nix® Creme Rinse.

If you or a member of your household has head lice, don't panic. Keep calm.

Anyone can get head lice - it has nothing to do with cleanliness or poor hygiene. Head lice are treatable and very rarely cause serious health problems.

### What are head lice?

- Head lice are small insects that live and feed on the human scalp.
- They may get as big as sesame seeds and are brown.
- Lice do not fly or jump from one person to another. They can only crawl.

### What are nits?

- Nits are lice eggs laid on the hair near the scalp. One louse may lay over 100 nits.
- Nits are oval shaped, tiny and yellow, brown or tan but appear white after hatching.
- Nits attach to hair with a waterproof glue-like substance that cannot be washed out or blown away.

Because nits (eggs) hatch in about one week, all nits must be removed to stop lice.

### How do head lice spread?

- Head lice spread easily from close head-to-head or hand-to-head contact with persons who have lice.
- They may also spread by sharing hats, helmets, scarves, headphones, brushes, combs, bedding and clothing.

### How do you know if you have lice?

- Itching is the most common symptom.
- Scratching behind the ears or the back of the neck is a sign that you should check for head lice.
- Scabs or blood spots may be seen.

### How do you prevent the spread of lice?

- Do not share or borrow personal items like combs, brushes, or headbands.
- Do not share or borrow hats, sweaters, coats, scarves, helmets, headphones, pillows or stuffed animals.
- Store hats in coat sleeves and hang coats separately, so that they do not touch other people's hats and coats.
- Wash under fingernails when you first see lice or nits (eggs).
- Check your child's head daily when you hear of a lice outbreak in day care or school.

## How to use NIX® Creme Rinse

### 1. Inspect



If you suspect head lice - check. Head lice may be hard to locate because they avoid light. Nits are easier to see.

- All household members should be checked by another person for lice and/or nits (eggs).
- Use a magnifying glass in bright light to help you see the lice and nits (eggs).
- Use a tool, such as a comb or two unsharpened pencils to lift and part the hair.

- Look for tiny nits near the scalp, beginning at the back of the neck and behind the ears.
- Small sections of hair (1-2 inches wide) should be examined at a time.
- Unlike dandruff, nits stick to the hair. Dandruff should move when lightly touched.
- If either lice or nits (eggs) are found, treat with Nix® Creme Rinse.

### 2. Treat

- Wash hair with a shampoo without conditioner. Do not use a shampoo that contains a conditioner or a conditioner alone since this may decrease the activity of Nix®. Rinse with water.



- Towel dry hair so it is damp but not wet.

- Shake the bottle of Nix® well.
- Completely saturate the hair and scalp with Nix®. Begin to apply Nix® behind the ears and at the back of the neck.



- Keep Nix® out of the eyes. Protect the eyes with a washcloth or towel.

- Leave Nix® on the hair for 10 minutes, but no longer.
- Rinse with warm water
- Towel dry hair and comb out tangles.

- If live lice are seen seven days or more after the first treatment, a second treatment should be given.

### 3. Remove Lice/Nits

Treatment kills lice but does not remove the nits.

- Remove nits by combing the hair with the special small tooth comb provided. Remaining nits may be removed by hand (using a throw-away glove), or cutting the nits out.



- Use the nit comb provided and make sure the hair remains slightly damp while removing nits.

- If the hair dries during combing, dampen it slightly with water.

- Part the hair into 4 sections. Work on one section at a time. Longer hair may take more time (1-2 hours).
- Start at the top of the head on the section you have picked.
- With one hand, lift a 1-2 inch wide strand of hair. Get the teeth of the comb as close to the scalp as possible and comb with a firm, even motion away from the scalp to the end of the hair.
- Use clips to pin back each strand of hair after you have combed out the nits.
- Clean the comb completely as you go. Wipe the nits from the comb with a tissue and throw away the tissue in a sealed plastic bag to prevent the lice from coming back.
- After combing, recheck the entire head for nits and repeat combing if necessary.
- Check the affected head daily to remove any nits that you might have missed.

### 4. Clean home and personal items

After using Nix® Creme Rinse, it is very important to clean personal items and your home to prevent the spread of lice. Nits may live away from the human head for about 7-12 days. Lice may live away from the human head for about 1 day.

- All personal head gear (hats, hair ribbons, etc.), scarves, coats, towels and bed linens should be washed in hot water (above 130°F), then dried in the dryer using the hottest cycle for at least 20 minutes.

- Personal combs, including nit combs, and brushes should be soaked in hot water (above 130°F) for at least 10 minutes.

- Personal articles such as clothing, bedspreads, blankets, pillows or stuffed animals that cannot be washed should be dry-cleaned or sealed tightly in a plastic bag for a period of at least 4 weeks. Items should be taken out of the plastic bag outdoors and shaken out very hard before using again.

- For anything you cannot wash, dry-clean or store in a plastic bag, spray with Nix® Lice Control Spray.

- Vacuum everywhere. Vacuum all carpets, mattresses, upholstered furniture and car seats that may have been used by infested household members.



### Warnings

#### For external use only

Do not use • on children under 2 months of age  
• near the eyes • inside the nose, ear, mouth, or vagina • on lice in eyebrows or eyelashes. See your doctor.

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

When using this product • keep eyes tightly closed and protect eyes with a washcloth or towel  
• If product gets into the eyes, immediately flush with large amounts of water • scalp itching or redness may occur.

Stop use and see a doctor if • breathing difficulty occurs • eye irritation occurs • skin or scalp irritation continues or infection occurs.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.  
If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Questions or comments?  
call 1-888-LICE LINE (1-888-542-3546),  
Monday to Friday, 9 AM - 5 PM EST [www.nixlice.com](http://www.nixlice.com)

Distributed by:  
INSIGHT Pharmaceuticals Corp.  
Tarrytown, NY 10591  
A Prestige Brands Company  
NX010601

**Nix**  
Permethrin 1%  
Lice Treatment Creme Rinse / Tratamiento de piojos Crema de enjuague

# Nix

Permethrin 1%

Tratamiento de piojos Crema de enjuague

## LOS HECHOS DE PIOJOS

Por favor, lea toda la información antes de usar la Crema de enjuague Nix®.

**Si usted o un miembro de su hogar tiene piojos de la cabeza, no entre en pánico. Mantenga la calma.**

Cualquier persona puede tener piojos - **No tiene nada que ver con la limpieza o mala higiene.** Los piojos de la cabeza son tratables y muy raramente causan problemas de salud graves.

### ¿Qué son los piojos de la cabeza?

- Los piojos son pequeños insectos que viven y se alimentan del cuero cabelludo humano.
- Pueden llegar a ser tan grandes como las semillas de sésamo y son marrones.
- Los piojos no vuelan ni saltan de una persona a otra. Sólo pueden gatear.

### ¿Qué son las liendres?

- Las liendres son huevos de piojos depositados en el cabello cerca del cuero cabelludo. Un piojo puede poner más de 100 nits.
- Las liendres son de forma ovalada, diminutas y amarillas, marrones o bronceadas pero aparecen blancas después de la eclosión.
- Unido al pelo con una sustancia impermeable pegajosa que no puede ser lavada o soplada lejos.

**Como las liendres (huevos) incuban en aproximadamente una semana, todas las liendres deben ser removidas para detener los piojos.**

### ¿Cómo se propagan los piojos de la cabeza?

- Los piojos de la cabeza se diseminan fácilmente de un contacto cercano de cabeza a cabeza o de mano a cabeza con personas que tienen piojos.
- También pueden extenderse compartiendo sombreros, cascos, bufandas, auriculares, cepillos, peines, ropa de cama y ropa.

### ¿Cómo sabes si tienes piojos?

- La picazón es el síntoma más común.
- Rascarse detrás de las orejas o de la parte posterior del cuello es una señal de que debe revisar si hay piojos.
- Se pueden observar costras o manchas de sangre.

### ¿Cómo se previene la propagación de los piojos?

- No comparta ni pida prestados artículos personales como peines, cepillos o cintas de cabeza.
- No comparta ni pida prestado sombreros, suéteres, abrigos, bufandas, cascos, auriculares, almohadas o peluches.
- Tienda sombreros en mangas de abrigo y cubre los abrigos por separado, para que no toquen los sombreros y abrigos de otras personas.

- Lave debajo de las uñas cuando vea por primera vez piojos o liendres (huevos).
- Revise la cabeza de su hijo diariamente cuando se entere de un brote de piojos en la guardería o en la escuela.

## Cómo utilizar la Crema de enjuague NIX®

### 1. Inspeccionar

Si usted sospecha de piojos de la cabeza - cheque. Los piojos de la cabeza pueden ser difíciles de localizar porque evitan la luz. Las liendres son más fáciles de ver.



- Todos los miembros del hogar deben ser revisados por otra persona para piojos y / o liendres (huevos).
- Utilice una lupa en la luz brillante para ayudarse a ver los piojos y las liendres (huevos).
- Use una herramienta, como un peine o dos lápices sin afilar para levantar y separar el pelo.
- Busque pequeñas liendres

cerca del cuero cabelludo, comenzando en la parte posterior del cuello y detrás de las orejas.

- Se deben examinar pequeñas secciones de pelo (1-2 pulgadas de ancho) a la vez.
- A diferencia de la caspa, las liendres se pegan al cabello. La caspa debe moverse cuando se toca ligeramente.
- Si se encuentran piojos o liendres (huevos), trate con la Crema de enjuague de Nix®.



### 2. Tratar

Lave el cabello con un champú sin acondicionador. No utilice un champú que contenga un acondicionador solo, ya que esto puede disminuir la actividad de Nix®. Enjuague con agua.

- Seque el cabello para que esté húmedo pero no mojado.
- Agite bien la botella de Nix®.
- Sature completamente el cabello con toalla y el cuero cabelludo con Nix®. Comience a aplicar Nix® detrás de las orejas y en la parte posterior del cuello.
- Mantenga Nix® fuera de los ojos. Proteja los ojos con un paño o una toalla.
- Deje actuar Nix® en el cabello durante 10 minutos, pero no más.
- Enjuague con agua tibia.
- Seque el cabello con toalla y peinar enredos.
- Si se observan piojos vivos siete días o más después del primer tratamiento, se debe administrar un segundo tratamiento.



### 3. Quitar Piojos / Nits

El tratamiento mata los piojos pero no quita las liendres.

- Retire las liendres peinando el cabello con el peine de diente especial suministrado. Las liendres que quedan pueden quitarse a mano (usando un guante desechable) o cortar las liendres.
- Utilice el peine suministrado y asegúrese de que el cabello permanezca ligeramente húmedo mientras retira las liendres.

- Si el cabello se seca durante el peinado, humedecelo ligeramente con agua.

- Parte el cabello en 4 secciones. Trabaje en una sección a la vez. El pelo más largo puede tomar más tiempo (1-2 horas).
- Comience por la parte superior de la cabeza en la sección que ha escogido.
- Con una mano, levante una malla de 1-2 pulgadas de ancho de cabello. Coloque los dientes del peine lo más cerca posible del cuero cabelludo y peine con un movimiento firme, incluso lejos del cuero cabelludo hasta el final del cabello.
- Utilice pinzas para sujetar cada mecha de cabello después de haber peinado las liendres.
- Limpie el peine completamente a medida que avanza. Limpie las liendres del peine con un pañuelo y deseche el tejido en una bolsa de plástico sellada para evitar que los piojos vuelvan.
- Después del peinado, vuelva a comprobar toda la cabeza para liendres y repita el peinado si es necesario.
- Revise la cabeza afectada diariamente para eliminar las liendres que pudieran haber perdido.



### 4. Limpie los artículos de casa y personales

Después de usar la Crema de enjuague Nix®, es muy importante limpiar artículos personales y su hogar para prevenir la propagación de piojos. Las liendres pueden vivir lejos de la cabeza humana por cerca de 7-12 días. Los piojos pueden vivir lejos de la cabeza humana por aproximadamente 1 día.

- Todo el equipo personal de la cabeza (sombreros, cintas para el cabello, etc.), bufandas, abrigos, toallas y ropa de cama deben ser lavados en agua caliente (por encima de 130 ° F), luego secados en la secadora utilizando los más calientes durante al menos 20 minutos.

- Los peines personales, incluidos los peines para peinar, y los cepillos deben ser empapados en agua caliente (por encima de 130 ° F) durante al menos 10 minutos.

- Los artículos personales como ropa, colchas, mantas, almohadas o animales de peluche que no puedan ser lavados deben ser limpiados en seco o sellados herméticamente en una bolsa de plástico por un período de al menos 4 semanas. Los artículos deben sacarse de la bolsa de plástico al aire libre y sacudirse con fuerza antes de volver a usarlos.

- Para cualquier cosa que no pueda lavar, limpiar en seco o guardar en una bolsa de plástico, rocíela con Nix® Lice Control Spray (rocío de control de piojos).
- Vacío en todas partes. Vacíe todas las alfombras, colchones, muebles tapizados y asientos de automóvil que pueden haber sido utilizados por los miembros de la familia infestados.



### Advertencias

#### Sólo para uso externo

No utilice • en niños menores de 2 meses de edad • cerca de los ojos • dentro de la nariz, el oído, la boca o la vagina • para piojos en las cejas o pestañas, consulte a su médico.

Pregunte a un médico antes de usarlo si tiene • alérgico a la ambrosía. Puede causar dificultad para respirar o un episodio asmático.

Cuando utilice este producto • Mantenga los ojos bien cerrados y proteja los ojos con un paño o una toalla. • Si el producto entra en los ojos, enjuáguelos inmediatamente con grandes cantidades de agua.

• Picazón en el cuero cabelludo o enrojecimiento.

Deje de usar y consulte a un médico si • ocurre dificultad para respirar • ocurre irritación en los ojos

• continúa la irritación de la piel o del cuero cabelludo o se produce una infección.

Si está embarazada o amamantando, pregúntele a un profesional de la salud antes de usarlo.

Mantenga fuera del alcance de los niños.

Si se irrita, busque ayuda médica o comuníquese con un centro de control de venenos (1-800-222-1222) inmediatamente.

¿Preguntas o comentarios?

llame 1-888-LICE LINE (1-888-542-3546), de lunes a viernes, 9 AM - 5 PM EST [www.nixice.com](http://www.nixice.com)

Distribuido por:  
INSIGHT Pharmaceuticals Corp.  
Tarrytown, NY 10591  
Una compañía de Prestige Brands

NIX010601



**Package Labeling:63471-3006-2**

**Active ingredient (in each fluid ounce) Purpose**  
Permethrin 280 mg (1%) ..... Lice treatment

**Use** treats head lice

**Warnings**  
**For external use only**

**Do not use** ■ on children under 2 months of age  
■ near the eyes ■ inside the nose, ear, mouth, or vagina ■ on lice in eyebrows or eyelashes. See your doctor.

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

**When using this product** ■ keep eyes tightly closed and protect eyes with a washcloth or towel ■ if product gets into the eyes, immediately flush with large amounts of water ■ 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

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

**1**  
**Treat**

✓ Kills lice and eggs in one application

✓ Prevents reinfestation\*  
\* For up to 14 days.

**2 FL OZ (59 mL)**

**Directions** See Consumer Information Insert for important directions on inspection for head lice, removing nits (eggs) and cleaning the home and personal items

**Treat** ■ wash hair with a shampoo without conditioner. Do not use a shampoo that contains a conditioner or a conditioner alone since this may decrease the activity of Nix®. Rinse with water. ■ towel dry hair so it is damp but not wet ■ shake the bottle of Nix® well ■ completely saturate the hair and scalp with Nix®. Begin to apply Nix® behind the ears and at the back of the neck. ■ keep Nix® out of the eyes. Protect the eyes with a washcloth or towel. ■ leave Nix® on the hair for 10 minutes, but no longer ■ rinse with warm water ■ towel dry hair and comb out tangles ■ if live lice are seen seven days or more after the first treatment, a second treatment should be given

**Other information** ■ Read all the directions on the Consumer Information Insert and warnings before use. Keep the carton. It contains important information ■ Store at 20° to 25° C (68° to 77° F)

**Inactive ingredients** canada balsam, cetyl alcohol, citric acid, FD&C yellow no. 6, hydrolyzed animal protein, hydroxyethylcellulose, isopropyl alcohol, methylparaben, polyoxyethylene 10 cetyl ether, propylene glycol, propylparaben, stearylaluminum chloride, water

**Questions?** 1-888-LICE LINE (1-888-542-3546) nixlice.com

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LOT: \_\_\_\_\_

EXP: \_\_\_\_\_

# NIX FAMILY PACK LICE KILLING CREME RINSE KIT

permethrin kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63471-3010
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63471-3010-0	1 in 1 KIT	11/15/2013	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BOTTLE	118 mL in 2

## Part 1 of 1

### NIX LICE KILLING CREME RINSE

permethrin rinse

## Product Information

<b>Item Code (Source)</b>	NDC:63471-3006(NDC:63736-030)
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<b>Route of Administration</b>	TOPICAL
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## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PERMETHRIN (UNII: 509F88P9SZ) (PERMETHRIN - UNII:509F88P9SZ)	PERMETHRIN	1 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
CANADA BALSAM (UNII: K304VI98I3)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CETETH-10 (UNII: LF9X1PN3XJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

**STEARALKONIUM CHLORIDE** (UNII: 00UO26BB88)

**WATER** (UNII: 059QF0KO0R)

### Product Characteristics

<b>Color</b>	orange (Light Orange)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63471-3006-2	1 in 1 CARTON		
1		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019918	11/15/2013	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019918	11/15/2013	

**Labeler** - Geodis Logistics LLC (877844097)