

PRODUCT MONOGRAPH  
INCLUDING PATIENT MEDICATION INFORMATION

**NIX® CRÈME RINSE**  
**Permethrin cream 1%**  
Topical Pediculicide and Ovicide  
ATC Code: P03AC04

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## RECENT MAJOR LABEL CHANGES

1 INDICATIONS, 4 DOSAGE AND ADMINISTRATION	01/2022
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## PART I: HEALTH PROFESSIONAL INFORMATION

### 1 INDICATIONS

NIX<sup>®</sup> CRÈME RINSE (Permethrin 1% cream) is indicated for the treatment of infestation with head lice and their nits (eggs).

#### 1.1 Pediatrics

**Pediatrics (two years and older):** Health Canada has authorized an indication for pediatric use (two years and older). Safety and effectiveness in children less than two years of age have not been established.

#### 1.2 Geriatrics

**Geriatrics (> 65 years of age):** No data are available to Health Canada; therefore, Health Canada has not authorized an indication for geriatric use.

### 2 CONTRAINDICATIONS

- NIX<sup>®</sup> CRÈME RINSE is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see 6 *DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING*.

### 3 SERIOUS WARNINGS AND PRECAUTIONS BOX

#### Serious Warnings and Precautions

- Pregnant or nursing patients should consult a health professional before use (see 7 [WARNINGS AND PRECAUTIONS, Pregnant Women](#) and 7 [WARNINGS AND PRECAUTIONS, Breast-feeding](#)).
- Patients allergic to any of the ingredients, synthetic pyrethroids or pyrethrin, or chrysanthemums should not use the drug (see 7 [WARNINGS AND PRECAUTIONS, General](#)).

### 4 DOSAGE AND ADMINISTRATION

#### 4.1 Dosing Considerations

- A single application is usually sufficient to eliminate a head lice infestation. The active ingredient in NIX<sup>®</sup> CRÈME RINSE persists on the hair for 10 days, even after subsequent washing with a conditioner-free shampoo. If you see live lice or nits after the first application, the residual effect should kill these. If you still see live lice or nits on the 7<sup>th</sup> day (or after) following the first application, NIX<sup>®</sup> CRÈME RINSE should be applied a second time.

- Cleaning of personal articles is also an important part of head lice management and may help prevent reinfestation. Personal belonging including recently worn clothing, towels and bed linens should be machine washed in hot water and dried using the hot cycle of the dryer for at least 20 minutes. Personal articles of clothing or bedding that cannot be washed may be dry cleaned or sealed in a plastic bag for a period of two weeks. Combs and brushes should be disinfected by soaking in hot water (above 130 °F/54 °C) for 5 to 10 minutes.
- Children should be advised not to use any borrowed combs or brushes, nor wear anyone else's clothes, especially hats.
- Inspect all family members from time to time for any new lice infestation. If a new infestation is found treat with NIX® CRÈME RINSE.

#### **4.2 Recommended Dose and Dosage Adjustment**

See Section 4.1 Dosing Considerations.

#### **4.3 Reconstitution**

Not applicable.

#### **4.4 Administration**

Directions

Adults and children 2 years of age and over:

1. Wash the hair with conditioner-free shampoo. Do not use conditioner. Rinse with water and towel dry thoroughly.
2. Shake NIX® CRÈME RINSE bottle well. Apply a sufficient amount of NIX® CRÈME RINSE (1/2 to 1 bottle) to thoroughly saturate the hair and scalp, especially behind the ears and at the base of the neck.
3. Leave NIX® CRÈME RINSE on the hair for 10 minutes.
4. Rinse NIX® CRÈME RINSE off hair with water.
5. Towel dry hair.
6. Comb hair with regular comb to remove tangles.
7. Remove nits: Part hair into sections; starting as close to the scalp as possible, remove the nits using the nit removal comb provided. Be sure to comb to the end of the hair shaft. The nit comb should be disinfected by soaking in hot water after each use. Inspect full head of hair thoroughly for any stray nits. The nit removal procedure should be repeated daily for the 7 days following treatment.

## 5 OVERDOSAGE

In the event of accidental ingestion of permethrin, please seek immediate medical attention. Symptoms of overdose may include dizziness, loss of appetite, nausea, vomiting, headache, weakness, seizures, and loss of consciousness.

For management of a suspected drug overdose, contact your regional poison control centre.

## 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Topical	Cream 1%	Balsam Canada, Cetyl Alcohol, Citric Acid, FD&C Yellow No. 6, Hydrolyzed Animal Protein, Hydroxyethyl Cellulose, Isopropyl Alcohol, Methylparaben, Poloxyethylene 10 Cetyl Ether, Propylene Glycol, Propylparaben, Stearalkonium Chloride, Water

NIX® CRÈME RINSE is packaged in a 59 mL HDPE bottle (inner (primary) package) and cardboard carton (outer (secondary) package). Each carton contains 2 bottles and 2 nit combs.

## 7 WARNINGS AND PRECAUTIONS

### General

Do not use if allergic to any of the ingredients, synthetic pyrethroids or pyrethrin, or chrysanthemums. Discontinue use if reaction occurs (see 3 SERIOUS WARNINGS AND PRECAUTIONS BOX).

NIX® CRÈME RINSE is for use when live lice or their eggs are present. It is not for prophylactic/regular use to prevent head lice.

NIX® CRÈME RINSE should be discontinued if hypersensitivity occurs.

Keep out of reach of children. For external use only. To prevent accidental ingestion by children, the remaining contents of NIX® CRÈME RINSE should be discarded after use.

In case of swallowing, consult your doctor or Poison Control Centre immediately.

It is important to ensure that the course of treatment is followed as directed because treatment failure has been reported when this has not occurred.

### Ophthalmologic

Permethrin is not irritating to eyes, but contact with the eyes should be avoided because other components of the product may cause marked irritation. If NIX® CRÈME RINSE comes in contact with the eyes, rinse eyes immediately with water.

## **Skin**

Head lice infestation is often accompanied by itching, redness, and swelling. Treatment with NIX® CRÈME RINSE may temporarily worsen these conditions. If skin irritation occurs and does not improve, consult a doctor.

## **7.1 Special Populations**

### **7.1.1 Pregnant Women**

There are no adequate or well-controlled studies in pregnant women. Consult a doctor before using this drug (see 3 SERIOUS WARNINGS AND PRECAUTIONS BOX).

### **7.1.2 Breast-feeding**

There are no adequate or well-controlled studies in breast-feeding women. Consult a doctor before using this drug (see 3 SERIOUS WARNINGS AND PRECAUTIONS BOX).

### **7.1.3 Pediatrics**

**Pediatrics (two years and older):** Health Canada has authorized an indication for pediatric use (two years and older). Safety and effectiveness in children less than two years of age have not been established. Do not use on children under 2 years of age.

### **7.1.4 Geriatrics**

**Geriatrics (> 65 years of age):** No data are available to Health Canada; therefore, Health Canada has not authorized an indication for geriatric use.

## **8 ADVERSE REACTIONS**

### **8.1 Adverse Reaction Overview**

In clinical studies, occasional itching has been known to occur. This is usually a consequence of head lice infestation itself, but may be temporarily worsened following treatment with NIX® CRÈME RINSE. Other reactions which are less frequent include: stinging/burning, tingling, numbness or discomfort, redness, swelling or rash of the scalp, paraesthesia, eczema, skin oedema, skin irritation, smarting, and pain of skin. All these reactions are usually mild and temporary.

### **8.2 Clinical Trial Adverse Reactions**

See 8.1 Adverse Reaction Overview.

### **8.2.1 Clinical Trial Adverse Reactions – Pediatrics**

Information is not available.

### **8.3 Less Common Clinical Trial Adverse Reactions**

Information is not available.

#### **8.3.1 Less Common Clinical Trial Adverse Reactions – Pediatrics**

Information is not available.

### **8.4 Abnormal Laboratory Findings: Hematologic, Clinical Chemistry and Other Quantitative Data**

Information is not available.

### **8.5 Post-Market Adverse Reactions**

Information is not available.

## **9 DRUG INTERACTIONS**

### **9.1 Drug Interactions Overview**

Information is not available.

### **9.2 Drug-Behavioural Interactions**

Information is not available.

### **9.3 Drug-Drug Interactions**

Information is not available.

### **9.4 Drug-Food Interactions**

Information is not available.

### **9.5 Drug-Herb Interactions**

Information is not available.

### **9.6 Drug-Laboratory Test Interactions**

Information is not available.



## **10 CLINICAL PHARMACOLOGY**

### **10.1 Mechanism of Action**

Permethrin is a synthetic pyrethroid, active against lice, ticks, mites, and fleas. It acts on the nerve cell membrane to disrupt the sodium channel current by which the polarization on the membrane is regulated. Delayed repolarization and paralysis of the pests are the consequences of this disturbance.

### **10.2 Pharmacodynamics**

Information on which the original indication was authorized is not available.

### **10.3 Pharmacokinetics**

Information on which the original indication was authorized is not available.

## **11 STORAGE, STABILITY AND DISPOSAL**

Store between 15 °C and 25 °C.

## **12 SPECIAL HANDLING INSTRUCTIONS**

None.

## PART II: SCIENTIFIC INFORMATION

### 13 PHARMACEUTICAL INFORMATION

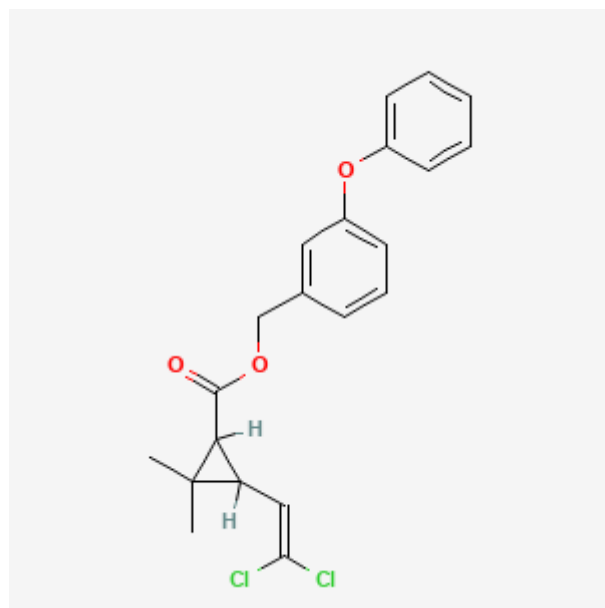
#### Drug Substance

Proper name: Permethrin

Chemical name: (3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate

Molecular formula and molecular mass:  $C_{21}Cl_2H_{20}O_3$  ; 391.3

Structural formula:



Physicochemical properties: Permethrin is a pale brown liquid. Relatively water insoluble. Used as an insecticide.

#### Product Characteristics:

Drug product is an orange liquid cream with a characteristic aromatic odour.

### 14 CLINICAL TRIALS

#### 14.1 Trial Design and Study Demographics

The clinical data on which the original indication was authorized is not available.

#### 14.2 Study Results

Please see Clinical Trials – Trials Design and Study Demographics Section.

## **15 MICROBIOLOGY**

No microbiological information is required for this drug product.

## **16 NON-CLINICAL TOXICOLOGY**

Information on which the product was authorized is not available.

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### NIX® CRÈME RINSE

##### Permethrin cream 1%

Read this carefully before you start taking **NIX® CRÈME RINSE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **NIX® CRÈME RINSE**.

#### Serious Warnings and Precautions

- Consult a doctor or pharmacist before use if you are pregnant or breastfeeding.
- Do not use **NIX® CRÈME RINSE** if you are allergic to any of the ingredients, synthetic pyrethroids or pyrethrin, or chrysanthemums.

#### What is NIX® CRÈME RINSE used for?

NIX® CRÈME RINSE (Permethrin cream) is indicated for:

- the treatment of infestation with head lice and their nits (eggs).

#### How does NIX® CRÈME RINSE work?

Permethrin affects the nervous system in insects, causing muscle spasms, paralysis and death.

#### What are the ingredients in NIX® CRÈME RINSE?

Medicinal ingredients: Permethrin

Non-medicinal ingredients: Balsam Canada, Cetyl Alcohol, Citric Acid, FD&C Yellow No. 6, Hydrolyzed Animal Protein, Hydroxyethyl Cellulose, Isopropyl Alcohol, Methylparaben, Poloxyethylene 10 Cetyl Ether, Propylene Glycol, Propylparaben, Stearalkonium Chloride, Water

#### NIX® CRÈME RINSE comes in the following dosage forms:

- Cream, 1% w/w

#### Do not use NIX® CRÈME RINSE if:

- hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take NIX® CRÈME RINSE. Talk about any health conditions or problems you may have, including if you:**

- are allergic to any of the ingredients, synthetic pyrethroids or pyrethrin, or chrysanthemums. Discontinue use if reactions occurs.
- are pregnant or breastfeeding.
- are elderly.

**Other warnings you should know about:**

- For external use only.
- Do not use in children under 2 years of age.
- Use NIX® CRÈME RINSE only when live lice or their eggs are present. Do not use regularly to prevent head lice.
- NIX® CRÈME RINSE is not irritating to eyes; however, if it should get into them, rinse eyes immediately with water.
- Avoid contact with the eyes, nose, mouth, mucous membranes or broken skin.
- Head lice infestation is often accompanied by itching, redness, and swelling. Treatment with NIX® CRÈME RINSE may temporarily worsen these conditions. If skin irritation occurs and does not improve, consult a doctor.
- To prevent accidental ingestion by children, the remaining contents of NIX® CRÈME RINSE should be discarded.
- For best results, use as directed. Incorrect use may cause treatment failure.
- **How to help prevent reinfestation**  
Cleaning of personal articles is also an important part of head lice management and may help prevent reinfestation. Personal belongings including recently worn clothing, towels and bed linens should be machine washed in hot water and dried using the hot cycle of the dryer for at least 20 minutes. Personal articles of clothing or bedding that cannot be washed may be dry cleaned or sealed in a plastic bag for a period of two weeks. Combs and brushes should be disinfected by soaking in hot water (above 130 ° F/54 °C) for 5 to 10 minutes.

Children should be advised not to use any borrowed combs or brushes, nor wear anyone else's clothes, especially hats. Inspect all family members from time to time for any new lice infestation. If a new infestation is found treat with NIX® CREME RINSE.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**How to take NIX® CRÈME RINSE:**

1. Wash the hair with conditioner-free shampoo. Do not use conditioner. Rinse with water and towel dry thoroughly.
2. Shake bottle well. Apply a sufficient amount of the product (1/2 to 1 bottle) to thoroughly saturate the hair and scalp, especially behind the ears and at the base of the neck.
3. Leave product on the hair for 10 minutes.
4. Rinse product off hair with water and towel dry hair.
5. Comb hair with regular comb to remove tangles.
6. Remove nits:
  - Part hair into sections, starting as close to the scalp as possible.
  - Remove the nits using the nit removal comb provided. Be sure to comb to the end of the hair shaft.
  - Disinfect the nit comb by soaking in hot water after each use.
  - Inspect full head of hair thoroughly for any stray nits.
7. Repeat nit removal procedure daily for the 7 days following treatment.

A single application is usually sufficient to eliminate a head lice infestation. The active ingredient in NIX® CRÈME RINSE persists on the hair for 10 days, even after subsequent washing with a conditioner-free shampoo.

If you see live lice or nits after the first application, the residual effect should kill these. If you still see live lice or nits on the 7th day (or after) following the first application, NIX® CREME RINSE should be applied a second time, as described above.

**Usual dose:**

Adults and children 2 years of age and over: Thoroughly saturate the hair and scalp with 1/2 to 1 bottle of NIX® CRÈME RINSE.

**Overdose:**

In case of accidental swallowing, please seek immediate medical attention. Symptoms of overdose may include dizziness, loss of appetite, nausea, vomiting, headache, weakness, seizures, and loss of consciousness.

If you think you, or a person you are caring for, have taken too much NIX® CRÈME RINSE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**What are possible side effects from using NIX® CRÈME RINSE?**

These are not all the possible side effects you may have when taking NIX® CRÈME RINSE. If you experience any side effects not listed here, tell your healthcare professional.

Occasional itching has been known to occur. This is usually a consequence of head lice infestation itself, but may be temporarily worsened following treatment with NIX® CRÈME RINSE.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop using drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>RARE</b>			
Swelling or redness	X		
Mild burning, stinging, tingling, numbness, or discomfort	X		
Allergic reaction Including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing			X
Rash on the scalp, feelings of pins and needle in the hands, arms, legs, or feet, eczema, skin swelling or irritation, or sharp pain	X		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

Store between 15 °C and 25 °C.

Keep out of reach and sight of children.

### **If you want more information about NIX® CRÈME RINSE:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <https://www.prestigebrands.com/products/skin-care/nix-lice-removal-products>, or by calling 1-888-542-3546.

This leaflet was prepared by Insight Pharmaceuticals LLC.

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