PEVIDERM PRAMOXINE HYDROCHOLRIDE 1%- pramoxine hydrochloride lotion
Stratus Pharmaceuticals Inc

Peviderm Pramoxine Hydrocholride 1%

Drug Facts

Active ingredient

Pramoxine Hydrochloride 1%

Purpose

External Analgesic

Uses

- for the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites, minor skin irritations and rashes due to poison ivy, poison oak, or poison sumac

Warnings

for external use only

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days

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

Keep out of reach of children.

If swallowed, get medical help or contact Poison Control Center immediately

Directions

- to open, hold cap tightly and turn pump counter-clockwise

Adults and children 2 years of age and older:

- apply to affected area not more than 3 to 4 times daily

Children under 2 years of age:

- consult a doctor

Other information

- Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature]

Inactive ingredients

Benzyl Alcohol, Carbomer 940, Cetyl Alcohol, Dimethicone, Glyceryl Stearate, Isopropyl Myristate, Petrolatum, PEG-8 Stearate, PEG-100 Stearate, Purified Water, Sodium Hydroxide, Stearic Acid.

Questions or comments?

Call us at **1-800-442-7882**

Distributed by:
STRATUS
PHARMACEUTICALS INC
Miami, Florida 33186

PRINCIPAL DISPLAY PANEL - 222 mL Bottle Box

NDC 58980-913-80

Steroid-Free & Fragrance-Free

PEVIDERM™
PRAMOXINE HYDROCHLORIDE 1%

ITCH RELIEF FOR SENSITIVE SKIN

EXTERNAL
ANALGESIC LOTION

Moisturizes and gently relieves
itch associated with:
Eczema and
Dry Sensitive Skin

Net 7.5 fl oz (222 mL)

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STRATUS PHARMACEUTICALS INC

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PH1(7.5)BX-202407

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PEVIDERM PRAMOXINE HYDROCHOLRIDE 1%

pramoxine hydrochloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58980-913
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Pramoxine Hydrochloride (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	Pramoxine Hydrochloride	1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
Glyceryl Stearate/PEG-100 Stearate (UNII: RD25J5V947)	
PEG-8 Stearate (UNII: 2P9L47VI5E)	
Calcium Chloride (UNII: M4I0D6VV5M)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
Cetyl Palmitate (UNII: 5ZA2S6B08X)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
White Petrolatum (UNII: B6E5W8RQJ4)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Benzyl Alcohol (UNII: LKG8494WBH)	
Sodium Hydroxide (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58980-913-80	1 in 1 BOX	11/01/2024	
1		222 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
OTC monograph drug	M017	11/01/2024	

Labeler - Stratus Pharmaceuticals Inc (789001641)

Establishment

Name	Address	ID/FEI	Business Operations
Tarmac Products Inc		059890491	MANUFACTURE(58980-913)

Revised: 11/2024 Stratus Pharmaceuticals Inc