

# **PRAMOXINE HYDROCHLORIDE ANORECTAL- pramoxine hydrochloride lotion**

## **Stratus Pharmaceuticals**

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### **Pramoxine Hydrochloride 1% Anorectal Lotion**

#### ***Drug Facts***

#### **Active ingredient**

Pramoxine HCL 1% w/w

#### **Purpose**

Local Anesthetic

#### **Use**

- for the temporary relief of itching and discomfort in the perianal area.

#### **Warnings**

**for external use only.**

#### **Do not**

- exceed the recommended daily dosage unless directed by a Physician.

#### **Do not**

- put this product into rectum by using fingers or any applicator.

#### **Stop use and ask a Physician if**

- Condition worsens
- Symptoms do not improve in 7 days
- Allergic reactions develop to ingredients in this product
- Symptoms being treated do not improve or subside or if redness, irritation, swelling, pain, bleeding or other symptoms develop or increase

**Keep this product out of the reach of children.** If swallowed, get medical attention or contact a Poison Control Center right away.

#### **Directions**

- Shake well before using.
- When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly.
- Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.
- Adults and children 12 years of age and older: apply to affected area up to five times daily.

- Children under 12 years of age, consult a Physician.

### **Inactive ingredients**

Carbomer 940, Cetyl Alcohol, Di-isopropyl Adipate, Dimethicone, Glycerin 99.7%, Lanolin Anhydrous, Light Mineral Oil, PEG 40 Stearate, Potassium Sorbate, Purified Water, Sorbic Acid, Stearic Acid, Stearyl Alcohol, Trolamine, Ultimate White Petrolatum.

### **Questions or comments?**

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

### ***Distributed by:***

**STRATUS**

PHARMACEUTICALS INC

Miami, Florida 33186

### **PRINCIPAL DISPLAY PANEL - 118 mL Bottle Box**

NDC 58980-522-40

ANORECTAL

PRAMOXINE  
HYDROCHLORIDE 1%

ANORECTAL

FAST RELIEF FROM ITCH  
AND DISCOMFORT

ANORECTAL  
(hemorrhoidal)  
LOTION

Net 4 fl oz (118 mL)

NDC 58980-522-40

**ANORECTAL**

**P**  
**RAMOXINE**  
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 PHARMACEUTICALS INC  
 Miami, Florida 33186

PH1AR(4)JL-202503



## PRAMOXINE HYDROCHLORIDE ANORECTAL

pramoxine hydrochloride lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58980-522
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Pramoxine Hydrochloride</b> (UNII: 88AYB867L5) (Pramoxine - UNII:068X84E056)	Pramoxine Hydrochloride	1 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 4Q93RCW27E)	
<b>CETYL PALMITATE</b> (UNII: 5ZA2S6B08X)	
<b>Glycerin</b> (UNII: PDC6A3C00X)	

<b>Light Mineral Oil</b> (UNII: N6K5787QVP)	
<b>WHITE PETROLATUM</b> (UNII: B6E5W8RQJ4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>PEG-40 MONOSTEARATE</b> (UNII: ECU18C66Q7)	
<b>Stearyl Alcohol</b> (UNII: 2KR89I4H1Y)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>DIISOPROPYL ADIPATE</b> (UNII: P7E6YFV72X)	
<b>Sorbic Acid</b> (UNII: X045WJ989B)	
<b>Water</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58980-522-40	1 in 1 BOX	11/01/2025	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58980-522-80	1 in 1 BOX	11/01/2025	
2		237 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	M015	11/01/2025	

**Labeler** - Stratus Pharmaceuticals (789001641)

### Establishment

Name	Address	ID/FEI	Business Operations
Tarmac Products		059890491	MANUFACTURE(58980-522)