PRAX- pramoxine hydrochloride lotion
AvPAK

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.

Pramoxine HCl 1% Lotion

Active Ingredient

pramoxine HCl 1% w/w

Purpose

local anesthetic

Use

for the temporary relief of discomfort and itch in the perianal area

Warnings

For external use only.

Do not

- exceed the recommended daily dosage unless directed by a doctor
- put this product into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens
- symptoms do not improve within 7 days
- allergic reactions develop to ingredients in this product
- symptom being treated does not subside or if redness, irritation, swelling, pain, bleeding, or other symptoms develop or increase

Keep out of reach of children.

If swallowed, seek medical attention or contact a Poison Control Center right away.

Directions

- Shake well before use.
- When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly.

- Adults and children 12 years of age and older: apply to affected area up to 5 times daily.
- Children under 12 years of age: consult a doctor.

Inactive Ingredients

Aloe Barbadensis Leaf Juice, Cetyl Alcohol, Glycerin, Glyceryl Stearate SE, Mineral Oil, PEG-100 Stearate, Phenoxyethanol, Purified Water, Stearyl Alcohol, White Petrolatum, Xanthan Gum

Package Label

Questions or comments call 1-855-361-3993.

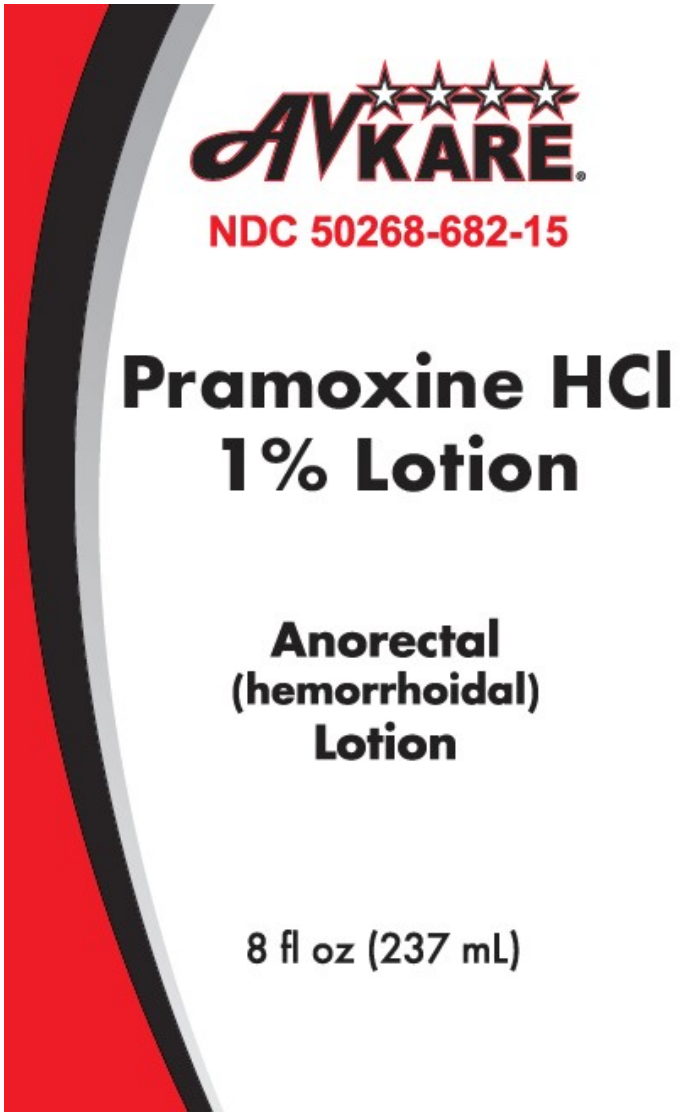
Manufactured for:

AvKARE

Pulaski, TN 38478

www.avkare.com

AV 01/2022



Drug Facts

Active Ingredient — **Purpose**
pramoxine HCl 1% w/w ..... local anesthetic

Use for the temporary relief of local discomfort and itch in the perianal area.

Warnings
For external use only.

■ Do not exceed the recommended daily dosage unless directed by a doctor. ■ Do not put this product into the rectum by using fingers or any mechanical device or applicator.

Stop use and ask doctor if
- condition worsens
- symptoms do not improve within 7 days
- allergic reactions develop to ingredients in this product
- symptom being treated does not subside or if redness, irritation, swelling, pain, bleeding, or other symptoms develop or increase

Keep out of reach of children. If swallowed, seek medical attention or contact a Poison Control Center right away.

Directions ■ Shake well before use.
- When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly.
- Adults and children 12 years of age and older: apply to affected area up to 5 times a day.
- Children under 12 years of age: consult a doctor.

Other Information
- Store at room temperature 15°-30°C (59°-86°F)
- Do not use if safety seal is torn or missing.

Inactive Ingredients Aloe Barbadensis Leaf Juice, Cetyl Alcohol, Glycerin, Glyceryl Stearate SE, Mineral Oil, PEG-100 Stearate, Phenoxyethanol, Purified Water, Stearyl Alcohol, White Petrolatum, Xanthan Gum

Questions or comments? • 1-855-361-3993

Manufactured for:
AvKARE
Pulaski, TN 38478
www.avkare.com
AV 01/2022

3 50268-682-15 0

PRAX
pramoxine hydrochloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50268-682
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
PETROLATUM (UNII: 4T6H12BN9U)	

STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50268-682-15	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/11/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	04/11/2022	

Labeler - AvPAK (832926666)

Revised: 4/2022 AvPAK