PRAMOXINE HYDROCHLORIDE - pramoxine hydrochloride aerosol, foam
Mayne Pharma

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 Hydrochloride 1%

ACTIVE INGREDIENT:

Pramoxine hydrochloride 1%.

INACTIVE INGREDIENTS:

Cetyl alcohol, emulsifying wax, methylparaben, polyoxyethylene C12-C14 ether, PPG5 Ceteth-20, propylene glycol, propylparaben, purified water, sorbitan trioleate, trolamine, and inert propellant: tetrafluoroethane.

INDICATION:

Use for the temporary relief of pain and itching associated with hemorrhoids.

DIRECTIONS: SHAKE WELL BEFORE USE.

Dispense Pramoxine Hydrochloride 1% onto a clean tissue or pad and apply externally to the affected area up to 5 times daily. See carton for additional directions for use.

WARNINGS:

Do not exceed the recommended daily dosage unless directed by a physician. If condition worsens or does not improve within 7 days, consult a physician. In case of rectal bleeding, consult a physician promptly. Do not put this product into the rectum by using fingers or any mechanical device or applicator. Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use immediately and consult a physician. Do not use in the eyes or nose. Do not apply to large areas of the body.

CAUTION: FOR EXTERNAL USE ONLY.

Do not insert any part of the aerosol container into the rectum. Contents of the container are under pressure. Do not burn or puncture the aerosol container. Do not store at temperatures above 49°C (120°F).

STORE UPRIGHT AT CONTROLLED ROOM TEMPERATURE 20°-25°C (68°-77°F). DO NOT REFRIGERATE.

Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Distributed by:
Mayne Pharma
Greenville, NC 27834

Net Wt. 0.53 oz (15 g)

HOLD UPRIGHT TO DISPENSE

PRINCIPAL DISPLAY PANEL - 15 g Container Carton

NDC 51862-180-15

Pramoxine
Hydrochloride 1%

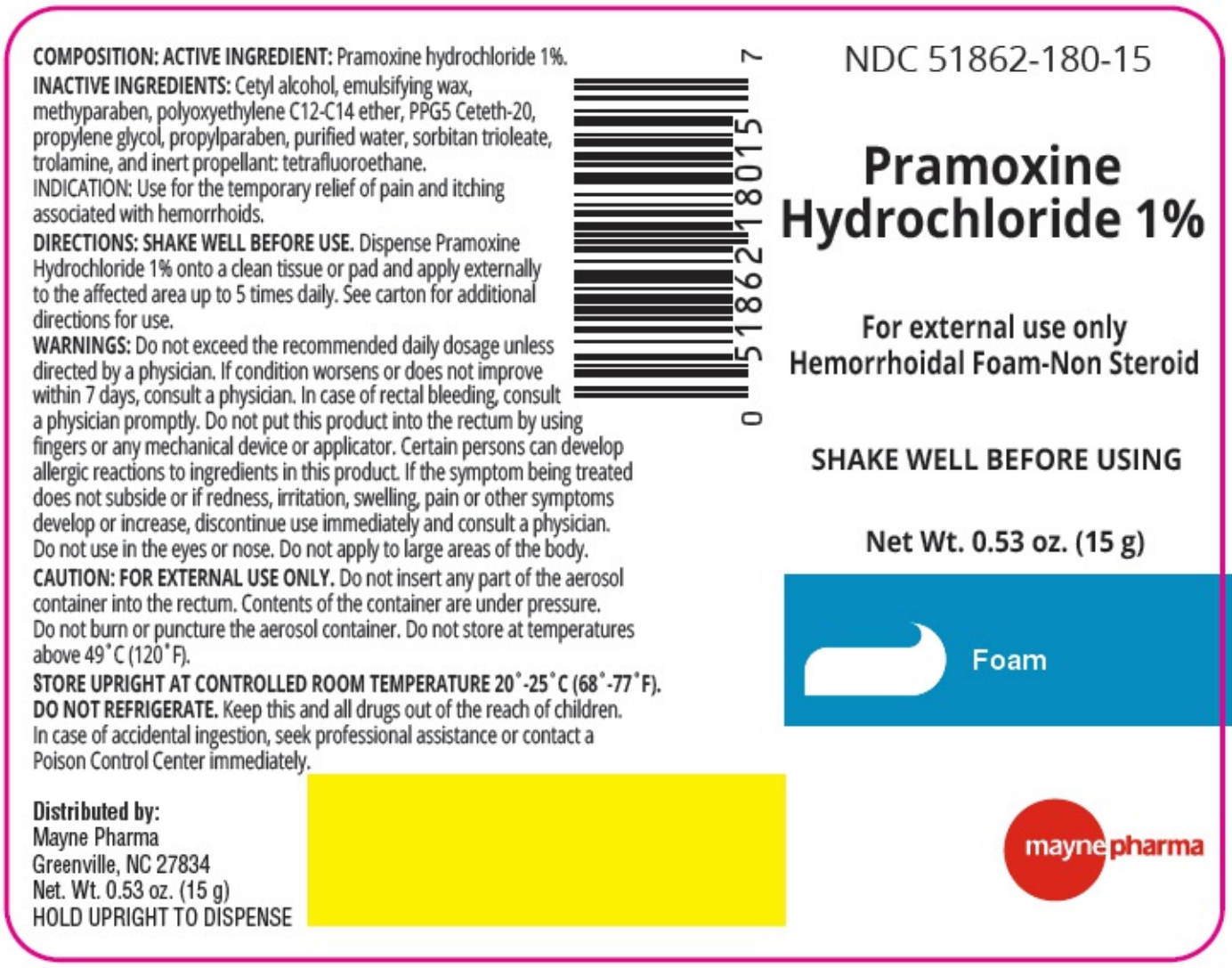
For external use only
Hemorrhoidal Foam-Non Steroid

SHAKE WELL BEFORE USING

Net Wt. 0.53 oz. (15 g)

Foam

mayne**pharma**



PRAMOXINE HYDROCHLORIDE
pramoxine hydrochloride aerosol, foam

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51862-180
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 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETYL ALCOHOL (UNII: 936JST6JCN)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CETETH-20 (UNII: I835H2IHHX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SORBITAN TRIOLEATE (UNII: QE6F49RPJ1)	
TROLAMINE (UNII: 9O3K93S3TK)	
TETRAFLUOROMETHANE (UNII: 94WG9QG0JN)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51862-180-15	1 in 1 CARTON	10/31/2011	
1		15 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	10/31/2011	

Labeler - Mayne Pharma (867220261)

Establishment

Name	Address	ID/FEI	Business Operations
Sciarra Laboratories, Inc.		824900369	MANUFACTURE(51862-180) , PACK(51862-180) , LABEL(51862-180)

Revised: 11/2017 Mayne Pharma