

PRAMOXINE HYDROCHLORIDE - pramoxine hydrochloride aerosol, foam
Physicians Total Care, Inc.

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.

proctofoam[®]
non-steroid
(pramoxine hydrochloride 1%)

Drug Facts

Active ingredient

Pramoxine hydrochloride 1%

Purpose

Local Anesthetic

Use

for the temporary relief of pain and itching associated with hemorrhoids

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. Do not insert any part of the aerosol container into the rectum.

Certain persons can develop allergic reactions to the 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 and consult a physician.

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

Directions

- Place cap on container. Shake well before use.
- Adults: 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 proctofoam[®].
- Dispense proctofoam[®] onto a clean tissue and apply externally to the affected area up to 5 times daily.
- Children under 12 years of age: consult a physician.

Other information

- Store upright at controlled room temperature 20° - 25°C (68° - 77°F); excursions permitted between 15° - 30°C (59° - 86°F).
- Do not refrigerate.
- Contents of the container are under pressure. Do not burn or puncture the aerosol container.
- Do not store at temperatures above 120°F (49°C).

Inactive ingredients

cetyl alcohol, glyceryl monostearate and PEG-100 stearate blend, methylparaben, polyoxyethylene 23 lauryl ether, polyoxyl 40 stearate, propylene glycol, propylparaben, purified water, trolamine and inert propellants: isobutane and propane.

Questions?

1-888-317-0001

ALAVEN®
PHARMACEUTICAL LLC
Marietta, GA 30067, USA

Rev. 08/08

Additional barcode labeling by:

Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

PRINCIPAL DISPLAY PANEL - 15 g Carton

NDC 54868-5865-0

**STORE UPRIGHT**

proctofoam®
non-
steroid

(pramoxine hydrochloride 1%)

hemorrhoidal foam

For temporary
relief of
hemorrhoidal
pain and itching

For External Use Only

15 g net wt (0.53 oz)

PRAMOXINE HYDROCHLORIDE

pramoxine hydrochloride aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-5865(NDC:68220-143)
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
pramoxine hydrochloride (UNII: 88AYB867L5) (pramoxine - UNII:068X84E056)	pramoxine hydrochloride	150 mg in 15 g

Inactive Ingredients

Ingredient Name	Strength
cetyl alcohol (UNII: 936JST6JCN)	
glyceryl monostearate (UNII: 230OU9XXE4)	
methylparaben (UNII: A2I8C7HI9T)	
polyoxyl 40 stearate (UNII: 13A4J4NH9I)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0K00R)	
trolamine (UNII: 9O3K93S3TK)	
isobutane (UNII: BXR49TP611)	
propane (UNII: T75W9911L6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-5865-0	1 in 1 CARTON		
1		15 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part346	02/22/2008	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

