

PROCTOFOAM NS- pramoxine hydrochloride aerosol, foam
Meda Pharmaceuticals

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.

Drug Facts

Active ingredient

Pramoxine hydrochloride 1%

Purpose

Local anesthetic

Use

for the temporary relief of pain and itching associated with hemorrhoids

Warnings

For external use only

When using this product

- 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
- do not insert any part of the aerosol container into the rectum

Stop use and ask a doctor if

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

If pregnant or breast-feeding,

ask a health professional before use.

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
- dispense 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° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 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 49°C (120°F)

Inactive ingredients

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

Questions?

1-888-350-1908

Distributed by:

Meda Pharmaceuticals Inc.

Somerset, New Jersey 08873-4120

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Principal Display Panel - 1%

NDC 0037-6823-15

TAMPER EVIDENT FEATURE: Do not use if Meda Pharmaceuticals® seal on ends of carton are broken or missing.

proctofoam® non-steroid
pramoxine hydrochloride 1%
hemorrhoidal foam

For temporary

**relief of
hemorrhoidal
pain and itching**

**STORE
UPRIGHT**

NET WT.
0.53 OZ (15 g)



PROCTOFOAM NS

pramoxine hydrochloride aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0037-6823
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)	
PEG-100 STEARATE (UNII: YD01N1999R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
LAURETH-23 (UNII: N72LMW566G)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
ISOBUTANE (UNII: BXR49TP611)	
PROPANE (UNII: T75W9911L6)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0037-6823-15	1 in 1 CARTON	08/18/2014	
1		15 g in 1 CANISTER; 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	08/18/2014	

Labeler - Meda Pharmaceuticals (051229602)