

PROCTOFOAM NS- pramoxine hydrochloride aerosol, foam
Viartis Specialty LLC

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.

Canonsburg, PA 15317 U.S.A.

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PROCTOFOAM is a registered trademark of Alaven Pharmaceutical LLC, a Viatrix Company..

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)

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Drug Facts (continued)

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Drug Facts (continued)

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

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MEDA PHARMACEUTICALS®

Canonsburg, PA 15317 U.S.A.

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117789

UC-82315-15-05



117789
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proctofoam[®] non-steroid
pramoxine hydrochloride 1%

hemorrhoidal foam

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Drug Facts (continued)
Inactive ingredients (oxy alcohol, glyceryl monostearate PEG-100 stearate blend, isobutane, methylparaben, polyoxyethylene 23 lauryl ether, polyoxy 40 stearate, propane, propylene glycol, propylparaben, purified water, trielaine
Questions? 1-888-350-1908

Drug Facts (continued)
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NDC 0037-6823-15

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pramoxine hydrochloride 1%

hemorrhoidal foam

For temporary relief of hemorrhoidal pain and itching

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0.53 OZ (15 g)

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MEDA
PHARMACEUTICALS[®]
Canonsburg, PA 15317 U.S.A.
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Lot:
Exp:
VARNISH FREE AREA: 1" x 1 1/2"



LOT/EXP

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 Drug	M346	08/18/2014	

Labeler - Viatris Specialty LLC (117455616)