

ANESTHETIC HEMORRHOIDAL WITH ALOE- pramoxine hydrochloride, zinc oxide ointment

Personal Care Products, 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.

Drug Facts Active Ingredient

Pramoxine HCL 1%

Zinc oxide 12.5%

Purpose

Local anesthetic

Protectant

Keep out of reach of children

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

Uses

temporarily shrinks hemorrhoidal tissue

temporarily relieves itching, burning and discomfort associated with hemorrhoids

Warnings

For external use only

Ask a doctor before use if you have - heart disease, high blood pressure, thyroid disease, diabetes, difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use, if you are presently taking a prescription drug for high blood pressure or depression

When using this product - do not exceed the recommended daily dosage unless directed by a doctor, do not use this product with an applicator, if the applicator into the rectum causes additional pain. Consult a doctor promptly.

Stop use and ask a doctor if - you experience bleeding, condition worsens or does not improve within 7 days, these may be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Directions

Direction for adults

when practical, cleanse the affected area by patting or blotting with an appropriate cleansing tissue.

Gently dry by patting or blotting with toilet tissue or soft cloth before application of this ointment, apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement

Children under 12 years or age, ask a doctor.

Other information

store between 59° and 86° F (15° and 30° C), close cap tightly after use, do not use if seal on tube is punctured or missing

Inactive ingredients

balsam peru, benzyl benzoate, calcium phosphate, cocoa butter, glyceryl monostearate, glyceryl monoleate, kaolin, mineral oil, Aloe vera extract

Product Label

DRUGSTORE - Rx

SMART WELLNESS

Anesthetic Hemorrhoidal Ointment With Aloe

Quick and soothing, pain relief from burning, itching and discomfort

Shrinks swollen hemorrhoidal tissue

NET WT. 1.5 OZ. (42 g)

DRUGSTORE-Rx

SMART WELLNESS delivers outstanding quality in healthcare products, at truly amazing prices. We employ the highest standard when searching the world to bring the best value to your doorstep. Use our products confidently, knowing that attention and care has gone into every item That's smart wellness!

Distributed by: PERSONAL CARE PRODUCTS, LLC

Troy, Michigan 484084 U.S.A. Code No.MH/DRUGS/KD-313 Made in India

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DUCTS, LLC

Code No.: MH/DRUGSKD-313

Made in India



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Ingredient Name	Strength
BALSAM PERU (UNII: 8P5F881OCY)	
BENZYL BENZOATE (UNII: N863NB338G)	
CALCIUM PHOSPHATE (UNII: 97Z1W3NDX)	
COCOA BUTTER (UNII: 512OYT1CRR)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
KAOLIN (UNII: 24H4NWX5CO)	
MINERAL OIL (UNII: T5L8T28FGP)	

GLYCERYL OLEATE (UNII: 4PC054V79P)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29500-2438-1	42 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part347	07/10/2013	

Labeler - Personal Care Products, Inc. (966155082)

Registrant - Personal Care Products, Inc. (966155082)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd.		916837425	manufacture(29500-2438)

Revised: 7/2020

Personal Care Products, Inc.