

AVEENO RESTORATIVE SKIN THERAPY ITCH RELIEF BALM- pramoxine hydrochloride cream

Johnson & Johnson Consumer 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.

Aveeno ® RESTORATIVE SKIN THERAPY Itch Relief Balm

Drug Facts

Active Ingredient

Pramoxine HCl (0.5%)

Purpose

External Analgesic

Use

For the temporary relief of itching associated with:

- minor skin irritations

Warnings

For external use only.

When using this product

- Avoid contact with the eyes.

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days

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

Directions

- Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.
- Children under 2 years of age: ask a doctor.

Other Information

Store at Room Temperature

Inactive Ingredients

Water, Glycerin, Distearyldimonium Chloride, Petrolatum, Isopropyl Palmitate, Cetyl Alcohol, Panthenol, Dimethicone, Avena Sativa (Oat) Kernel Flour, Benzyl Alcohol, Cetyl Hydroxyethylcellulose, Chlorphenesin, Steareth-20, Aloe Barbadensis Leaf Extract, Sodium Chloride, Avena Sativa (Oat) Kernel Extract

Questions?

Call toll-free **866-428-3366** or 215-273-8755 (collect) or visit www.aveeno.com

Distributed by:

JOHNSON & JOHNSON

CONSUMER INC.

Skillman, NJ 08558

PRINCIPAL DISPLAY PANEL - 113 g Tube Carton

DERMATOLOGIST RECOMMENDED

NEW

Aveeno®

RESTORATIVE

SKIN THERAPY

SENSITIVE, DISTRESSED, DRY SKIN

Itch Relief Balm

Pramoxine HCL external analgesic

prebiotic oat

concentrate,

aloe & pro-vit B5

instantly soothes

& helps relieve itch

net wt. 4 oz (113g)

GLUE - NO COATING

Aveeno. itch relief balm

FORMULATED WITH

Pramoxine HCl
helps relieve itch from minor skin irritation

Prebiotic Oat Concentrate
a powerful antioxidant known to moisturize
& soothe dry skin

Aloe
known to soothe skin

Pro-Vitamin B5
helps heal dry skin

FORMULATED WITHOUT

Fragrance · Parabens
Steroids · Phthalates

This non-greasy balm absorbs quickly to
instantly soothe skin



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Itch Relief Balm

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Skillman, NJ 08558
● J&JCI 2020



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Varnish free area



AVEENO RESTORATIVE SKIN THERAPY ITCH RELIEF BALM

pramoxine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69968-0637
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
PETROLATUM (UNII: 4T6H12BN9U)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PANTHENOL (UNII: WW9CM0067Z)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
OATMEAL (UNII: 8PI54V663Y)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
STEARETH-20 (UNII: L0Q8IK9E08)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
OAT (UNII: Z6J799EAJK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0637-4	1 in 1 CARTON	08/01/2020	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph not final	part348	08/01/2020	

Labeler - Johnson & Johnson Consumer Inc. (118772437)

Revised: 1/2023

Johnson & Johnson Consumer Inc.