

AVEENO CALM PLUS RESTORE 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 Calm Plus Restore Itch Relief Balm

Drug Facts

Active ingredient

Pramoxine HCl (0.5%)

Purpose

External Analgesic

Uses

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?

866-428-3366; Outside US, dial collect **215-273-8755** www.aveeno.com

Distributed by:

JOHNSON & JOHNSON

CONSUMER INC.

Skillman, NJ 08558

PRINCIPAL DISPLAY PANEL - 113g Tube Carton

NEW

Aveeno®

Calm +

Restore

ITCH RELIEF

BALM

Pramoxine HCl external analgesic

Sensitive,

Delicate Skin

Instantly soothes

and helps relieve itch

FRAGRANCE FREE

DERMATOLOGIST RECOMMENDED BRAND

PREBIOTIC OAT, ALOE, PRO-VIT B5

net wt.

4 OZ (113 g)



AVEENO
Calm + Restore[®] Itch Relief Balm
Instantly soothes and helps
relieve itch

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AVEENO
Calm + Restore[®] Itch Relief Balm
This non-greasy balm absorbs
quickly to instantly soothe skin

CARE FOR SKIN

Formulated with:
Pramoxine HCL to help relieve itch from minor skin irritation
Prebiotic Oat Concentrate, a powerful antioxidant known to moisturize & soothe dry skin
Aloe to soothe skin
Pro-Vitamin B5 to help heal dry skin

- fragrance free
 - paraben free
 - steroid free
 - phthalate free
- Oats are Non-GMO

CARE FOR PLANET

Learn more about our sustainability efforts at Aveeno.com

Aveeno[®]

NEW

**Calm +
Restore**
ITCH RELIEF
BALM

Pramoxine HCl external analgesic

**Sensitive,
Delicate Skin**

Instantly soothes
and helps relieve itch

FRAGRANCE FREE



net wt.
4 oz (113g)

ACTUAL SIZE



AVEENO CALM PLUS RESTORE ITCH RELIEF BALM

pramoxine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69968-0796
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)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PANTHENOL (UNII: WW9CM0O67Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
STEARETH-20 (UNII: L0Q8IK9E08)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
OATMEAL (UNII: 8PI54V663Y)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
OAT (UNII: Z6J799EAJK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0796-4	1 in 1 CARTON	07/03/2023	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/03/2023	

Labeler - Johnson & Johnson Consumer Inc. (118772437)

Revised: 1/2023

Johnson & Johnson Consumer Inc.