

AVEENO CALAMINE AND PRAMOXINE HYDROCHLORIDE ANTI ITCH- ferric oxide red, zinc oxide, and 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 Calamine & Pramoxine HCl Anti-Itch Cream

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Calamine 3%	Skin Protectant
Pramoxine HCl 1%	External Analgesic

Uses

- For temporary relief of pain and itching associated with minor burns, sunburns, minor cuts, scrapes, insect bites, minor skin irritations, rashes due to poison ivy, poison oak, or poison sumac
- Dries the oozing and weeping of poison ivy/oak/sumac

Warnings

For external use only

When using this product Do not get into 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
- Do not apply to wounds or damaged skin.
- Do not bandage tightly

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

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: consult a doctor.

Other Information

- STORE AT ROOM TEMPERATURE

Inactive ingredients

avena sativa (oat) kernel extract, avena sativa (oat) kernel flour, avena sativa (oat) kernel oil, camphor, cetyl alcohol, dimethicone, distearyldimonium chloride, glycerin, isopropyl palmitate, methylparaben, petrolatum, sodium chloride, water

Questions?

1-866-428-3366 or visit www.aveeno.com

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Consumer Companies, Inc.
Skillman, NJ 08558-9418

PRINCIPAL DISPLAY PANEL - 28g Tube Carton

Dermatologist Recommended

Aveeno®

ACTIVE NATURALS®

Calamine & Pramoxine HCl

ANTI-ITCH CREAM

External Analgesic/Skin Protectant

Steroid Free

Effectively relieves Itch from:

Poison Ivy/Oak/Sumac and Insect Bites

Soothes:

Chicken Pox Rash and Allergic Itch

New

Itch Relieving

Formula

Fast-Acting, Soothing Itch Relief

Dries out weepy rashes

NET WT 1 OZ (28g)

With Triple Oat Complex



Dermatologist Recommended

Aveeno[®]

ACTIVE NATURALS[®]

Calamine & Pramoxine HCl ANTI-ITCH CREAM

External Analgesic/Skin Protectant

Steroid Free

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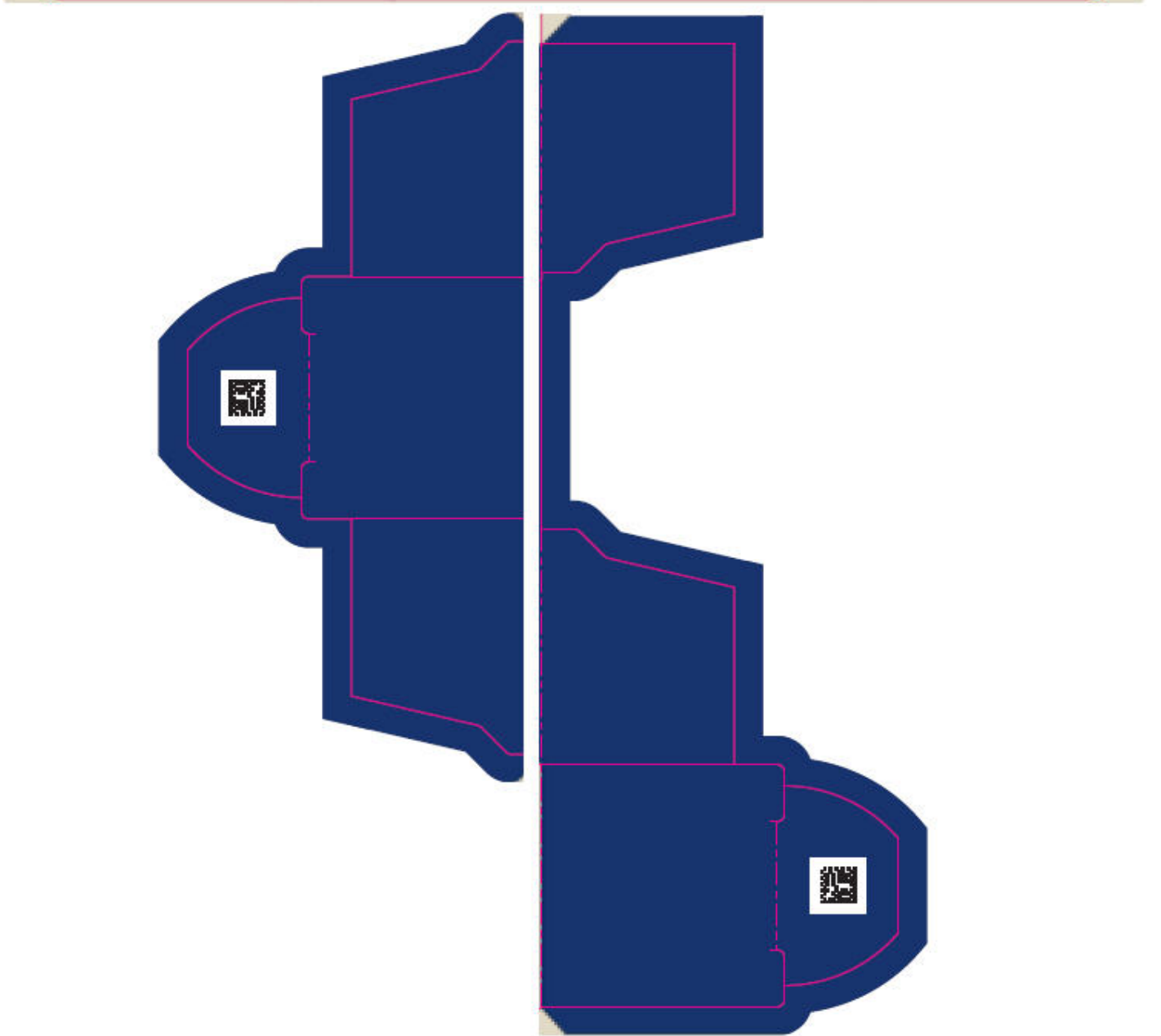
See end flap for lot code and expiration date

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Other information
STORE AT ROOM TEMPERATURE
Inactive ingredients Avena Sativa (Oat) Kernel Extract, Avena Sativa (Oat) Kernel Flour, Avena Sativa (Oat) Kernel Oil, Camphor, Cetyl Alcohol, Dimethicone, Distearoyldimonium Chloride, Glycerin, Isopropyl Palmitate, Methylparaben, Petrolatum, Sodium Chloride, Water
Questions? 1-866-428-3366 or visit www.aveeno.com

Warnings
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When using this product • Do not get into eyes
Stop use and ask a doctor if
• Condition worsens
• Symptoms last more than 7 days or clear up and occur again within a few days
• Do not apply to wounds or damaged skin
• Do not bandage tightly
• For temporary relief or pain and itching associated with minor burns, sunburns, minor cuts, scrapes, insect bites, minor skin irritations, rashes due to poison ivy, poison oak or poison sumac.
• Dries the oozing and weeping of poison ivy/oak/sumac



AVEENO CALAMINE AND PRAMOXINE HYDROCHLORIDE ANTI ITCH
 ferric oxide red, zinc oxide, and pramoxine hydrochloride cream

AVENO.
ACTIVE NATURALS.

Calamine & Pramoxine HCl Anti-Itch Cream
 Fast-acting, soothing itch relief. Dries out weepy rashes.

Drug Facts
Active Ingredient
 Calamine (3%)Skin Protectant
 Pramoxine HCl (1%)External Anesthetic

Purpose
 Skin Protectant
 External Anesthetic

Uses
 Pramoxine HCl (1%)External Anesthetic

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: consult a doctor

Drug Facts (continued)
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Essential ACTIVE NATURALS:
 • Pure oat essence to help soothe skin irritation and redness
 • Skin-soothing natural colloidal oatmeal

Discover AVEENO® ACTIVE NATURALS®. Simply put, ACTIVE NATURALS® are ingredients derived from nature and uniquely formulated to reveal skin's natural health and beauty.

AVENO.
 dermatologist recommended for over 50 years.

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58232-9911
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Ferric Oxide Red (UNII: 1K09F3G675) (Ferric Oxide Red - UNII:1K09F3G675)	Ferric Oxide Red	0.6 mg in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	29.4 mg in 1 g
Pramoxine Hydrochloride (UNII: 88AYB867L5) (Pramoxine - UNII:068X84E056)	Pramoxine Hydrochloride	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Oat (UNII: Z6J799EAJK)	
Oatmeal (UNII: 8PI54V663Y)	
Oat Kernel Oil (UNII: 3UVP41R77R)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Dimethicone (UNII: 92RU3N3Y1O)	
Distearyldimonium Chloride (UNII: OM9573ZX3X)	
Glycerin (UNII: PDC6A3C0OX)	
Isopropyl Palmitate (UNII: 8CRQ2TH63M)	
Methylparaben (UNII: A2I8C7HI9T)	
Petrolatum (UNII: 4T6HI2BN9U)	
Sodium Chloride (UNII: 451W47IQ8X)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58232-9911-1	1 in 1 CARTON	06/20/2013	12/01/2023
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:58232-9911-2	2.8 g in 1 PACKET; Type 0: Not a Combination Product	06/20/2013	12/01/2023

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	06/20/2013	12/01/2023

Labeler - Johnson & Johnson Consumer Inc. (002347102)