AVEENO ANTI-ITCH CONCENTRATED- zinc oxide, ferric oxide red, and pramoxine hydrochloride lotion
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 ® Anti-Itch CONCENTRATED LOTION

Drug Facts

Active ingredients	**Purpose**
Calamine 3%	Skin Protectant
Pramoxine HCl 1%	External Analgesic

Uses

- For temporary relief of pain and itching associated with:
  - minor burns
  - sunburn
  - 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.

Do not use

- on wounds or damaged skin

When using this product

- do not get into eyes
- do not bandage tightly

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

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, Dimethicone, Camphor, Methylparaben, Sodium Chloride, Avena Sativa (Oat) Kernel Oil, Avena Sativa (Oat) Kernal Flour, Avena Sativa (Oat) Kernel Extract

Questions?

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

Distributed by: **JOHNSON &**
JOHNSON CONSUMER INC.
Skillman, NJ 08558

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

Dermatologist
Recommended

Aveeno ®

Anti-Itch
CONCENTRATED LOTION
External Analgesic/Skin Protectant

Fast-Acting,
Soothing Itch Relief of:
Poison Ivy/Oak/Sumac,
Insect Bites

Soothes Chicken Pox Rash
and Allergic Itches

Aveeno ®
Dermatologist recommended
for over 65 years

with Triple
Oat Complex

4 fl. oz. (118 mL)

AVEENO ANTI-ITCH CONCENTRATED

zinc oxide, ferric oxide red, and pramoxine hydrochloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69968-0475
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	29.4 mg in 1 mL

FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	0.6 mg in 1 mL
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL

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)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
OAT KERNEL OIL (UNII: 3UVP41R77R)	
OATMEAL (UNII: 8PI54V663Y)	
OAT (UNII: Z6J799EAJK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0475-4	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/01/2019	

Labeler - Johnson & Johnson Consumer Inc. (118772437)

Revised: 1/2023 Johnson & Johnson Consumer Inc.