

MEDICATED- menthol, zinc oxide powder

Vi-Jon

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 Ingredients

Menthol 0.15%

Zinc oxide 1.0%

Purpose

External analgesic

Skin protectant

Uses

Uses for the temporary relief of pain and itching due to:

- minor cuts
- sunburn
- insect bites
- poison ivy
- poison oak
- poison sumac
- scrapes
- minor burns
- minor skin irritations

dries the oozing and weeping of:

- poison ivy
- poison oak
- poison sumac

Warnings

For external use only

When using this product

avoid contact with the eyes

Stop use and ask a doctor if

condition worsens, or if 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 - do not use, consult a doctor

- for best results dry skin thoroughly before applying

Inactive ingredients

talc, acacia, eucalyptol, methyl salicylate, salicylic acid, thymol, zinc stearate

disclaimer

This product is sold by weight, not by volume. Some settling may occur during handling and shipping

Made in the USA with US and foreign components

Adverse Reactions

Vi-Jon

One Swan Drive

Smyrna, TN 37167

Principal Display Panel

NDC 0869-0551-38

SWAN

medicated

Body Powder

skin protectant/topical analgesic

triple action

- Cooling
- Absorbing
- Itch Relieving

Compare to Active Ingredients of Gold Bond Medicated Body Powder

NET WT 10 OZ (283 G)

NDC 0869-0551-38



SINCE 1940

medicated

Body Powder

skin protectant / topical analgesic

triple action

- ▶ Cooling
- ▶ Absorbing
- ▶ Itch Relieving

Compare to Active Ingredients of Gold Bond® Medicated Body Powder

NET WT 10 OZ (283 g)

55138 4V F2

MEDICATED

menthol, zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0869-0551
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.5 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
ACACIA (UNII: 5C5403N26O)	
EUCALYPTOL (UNII: RV6J6604TK)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
THYMOL (UNII: 3J50XA376E)	
ZINC STEARATE (UNII: H92E6QA4FV)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0869-0551-38	283 g in 1 BOTTLE, DISPENSING		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/12/2003	

Labeler - Vi-Jon (790752542)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
M+K Packaging		047022405	manufacture(0869-0551)