

## **MEDICATED- menthol, zinc oxide powder**

**DZB Brands, LLC**

*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.*

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### **Drug Facts**

#### **Active ingredients**

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Menthol 0.15%

Zinc oxide 1.0%

#### **Purpose**

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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**

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**For external use only**

**When using this product**

**When using this product** avoid contact with the eyes

**Stop use**

**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**

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

**Directions**

**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**

**Inactive ingredients** talc, acacia, eucalyptol, methyl salicylate, salicylic acid, thymol, zinc stearate

**Disclaimer**

This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Gold Bond

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

**Adverse reactions**

Distributed by: DZA Brands, LLC

2110 Executive Drive

Salisbury, NC 28147

For Product questions or concerns

contact us at 1-866-322-2439. Please include UPC number and code from package

**Principal Display Panel**

Healthy

Accents

medicated

body powder

external analgesic

cooling - absorbing- itch relieving

Compare to the active ingredients of Gold Bond Medicated Body Powder

NET WT 10 OZ (283 g)

healthy accents™

# medicated body powder

skin protectant  
external analgesic

cooling • absorbing • itch relieving

compare to the active ingredients of Gold Bond® Medicated Body Powder\*



NET WT 10 OZ (283 g)

10011635A

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<b>Active Ingredients</b>	<b>Purpose</b>
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Zinc oxide 1.0%	Skin protectant
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<b>Warnings</b>	
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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	
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Solsbury, NC 28147

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10011635A

## MEDICATED

menthol, zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55316-551
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:55316-551-38	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	02/01/2011	

**Labeler** - DZB Brands, LLC (090322194)**Registrant** - Vi-Jon (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
M+K Packaging		047022405	manufacture(55316-551)

Revised: 1/2013

DZB Brands, LLC