# GOLD BOND MEDICATED ORIGINAL STRENGTH BODY- menthol powder Navajo Manufacturing Company 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.

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#### Gold Bond Medicated Original Strength Body Powder - Reformulated

Gold Bond Medicated
Original Strength Body Powder
Drug Facts

#### Active ingredient

Menthol 0.15%

#### **Purpose**

Anti-itch

#### Uses

temporarily relieves the pain and itch associated with:

■ minor cuts ■ sunburn ■ insect bites ■ scrapes ■ minor burns ■ minor skin irritations

## Warnings

For external use only

## When using this product

■ avoid contact with 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
- redness, irritation, swelling or pain persists or increases

## Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

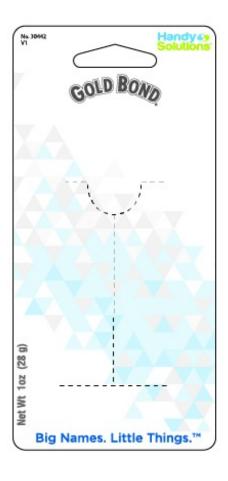
#### **Directions**

- adults and children 2 years and older: apply freely up to 3 or 4 times daily
- **children under 2 years:** ask a doctor
- for best results dry skin thoroughly before applying

### Inactive ingredients

zea mays (corn) starch, zinc oxide, acacia senegal gum, silica, tricalcium phosphate, eucalyptol, methyl salicylate, salicylic acid, zinc stearate, thymol

#### PRINCIPAL DISPLAY PANEL





#### **GOLD BOND MEDICATED ORIGINAL STRENGTH BODY**

menthol powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67751-225(NDC:41167-0110)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.15 g in 100 g	

Inactive Ingredients				
Ingredient Name	Strength			
STARCH, CORN (UNII: O8232NY3SJ)				
ZINC OXIDE (UNII: SOI2LOH54Z)				
<b>ACACIA</b> (UNII: 5C5403N26O)				
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)				
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)				
EUCALYPTOL (UNII: RV6J6604TK)				
METHYL SALICYLATE (UNII: LAV5U5022Y)				
SALICYLIC ACID (UNII: O414PZ4LPZ)				
ZINC STEARATE (UNII: H92E6QA4FV)				
THYMOL (UNII: 3J50XA376E)				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-225- 01	1 in 1 BLISTER PACK	03/01/2021	
1		28 g in 1 BOTTLE; 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	03/01/2021	

## Labeler - Navajo Manufacturing Company Inc. (091917799)

Establishment			
Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-225) , repack(67751-225)

Revised: 3/2023 Navajo Manufacturing Company Inc.