

BODY- menthol powder

Major Pharmaceuticals

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 ingredient

Menthol 0.15%

Purpose

External analgesic

Uses

for 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

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

Zea mays (corn) starch, sodium bicarbonate, tricalcium phosphate, zinc oxide, acacia seyal gum, eucalyptol, methyl salicylate, salicylic acid, thymol, zinc stearate

Questions

Call 1-800-616-2471

disclaimers

This product is not manufactured or distributed by Chattem, distributor of Gold Bond Medicated Body Powder.

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

Adverse Reaction

Distributed By

MAJOR PHARMACEUTICALS

31778 ENTERPRISE DRIVE

LIVONIA, MI 48150 USA

Principal Display Panel

NDC 0904-6348-77

MAJOR

MEDICATED

BODY POWDER

Pain Relieving Powder

WITH ESSENTIAL OILS

Compare to Gold Bond Medicated

Body Powder

Soothes

Absorbs Moisture

Menthol 0.15 % Anti-Itch

NET WT 10 OZ (283 g)

NDC 0904-6348-77

 **MAJOR**[®]

MEDICATED

**BODY
POWDER**

Pain Relieving Powder

WITH ESSENTIAL OILS

**Compare to Gold Bond Medicated
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L0013803FA

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NET WT 10 OZ (283 g)

L0013803FA

BODY

menthol powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6348
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

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
GUM TALHA (UNII: H18F76G097)	
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:0904-6348-77	283 g in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/01/2013	

Labeler - Major Pharmaceuticals (191427277)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
MK Packaging		047022405	manufacture(0904-6348)

Revised: 4/2018

Major Pharmaceuticals