

**STUDIO 35 EXTERNAL ANALGESIC MEDICATED BODY- menthol and zinc oxide powder
Walgreen Co**

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.

Active Ingredients

Menthol 0.15%

Zinc Oxide 1.0%

Purpose

External analgesic

Skin protectant

Uses

for the temporary relief of pain and itching associated with:

- minor cuts
- sunburn
- insect bites
- 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 no more than 3 to 4 times daily
- children under 2 years of age: consult a doctor
- for best results, dry area thoroughly before applying

Inactive Ingredients

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

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

Questions or comments?

Call 1-800-925-4733

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200 WILMOT RE., DEERFIELD, IL 60015

100% SATISFACTION GUARANTEED

Principal Display Panel

Studio 35

EXTERNAL ANALGESIC

MEDICATED BODY POWDER

PAIN RELIEVING POWDER

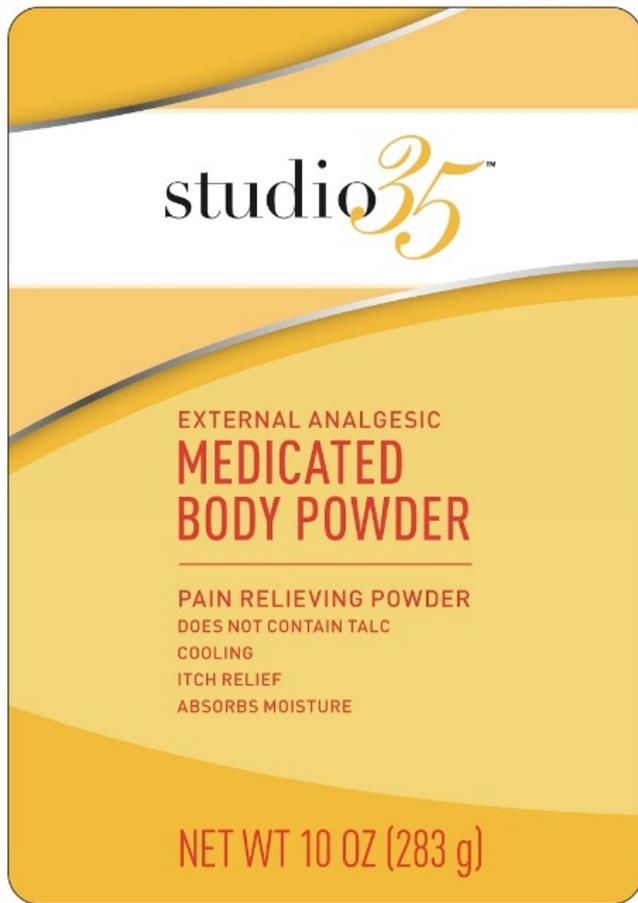
DOES NOT CONTAIN TALC

COOLING

ITCH RELIEF

ABSORBS MOISTURE

NET WT 10 OZ (283 g)



Drug Facts		
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ORG0117-F DNH/C-92

STUDIO 35 EXTERNAL ANALGESIC MEDICATED BODY

menthol and zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0552
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 CATION - UNII:13S1S8SF37)	ZINC CATION	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	
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:0363-0552-38	283 g in 1 BOTTLE; Type 0: Not a Combination Product	02/07/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/07/2017	

Labeler - Walgreen Co (008965063)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(0363-0552)

Revised: 2/2017

Walgreen Co