AMMENS MEDICATED POWDER SHOWER FRESH- zinc oxide powder Idelle Labs, Ltd

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.

AMMENS® MEDICATED POWDER - SHOWER FRESH

Active ingredient

Zinc Oxide 5%

Purpose

Skin Protectant

Use

dries the oozing and weeping of poison:

- ivy
- oak
- sumac

Warnings

For external use only.

When using this product

• do not get into eyes

Stop use and ask doctor, if

- condition worsens
- symptoms last 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

Apply as needed

Inactive ingredients:

Zea Mays (Corn) Starch, Tricalcium Phosphate, Fragrance, Aloe Barbadensis Leaf Extract

Questions?

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PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

AMMENS®

NEW 100% TALC FREE

TRUSTED FOR MORE THAN 100 YEARS

MEDICATED POWDER

SHOWER FRESH with ALOE

Soothes

Relieves

Absorbs

Net Wt 11oz (311g)





Ammens® Shower Fresh
Medicated Powder is specially
formulated with a blend of zinc
oxide and highly absorbent corn
starch to help soothe skin while
absorbing excess moisture. Enriched
with aloe, the formula delivers all-over
freshness and comfort. Use after bath
or shower for all-day dryness

and silky-soft freshness.

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Questions?

1-800-487-7273

AMMENS MEDICATED POWDER SHOWER FRESH

zinc oxide powder

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:41595-1061

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC O XIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	5 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
STARCH, CORN (UNII: O8232NY3SJ)			
TRICALCIUM PHO SPHATE (UNII: K4C08XP666)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			

l	Packaging					
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
l	1 NDC:41595-1061-1	311 g in 1 CANISTER; Type 0: Not a Combination Product	12/31/2017			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part347	12/31/2017			

Labeler - Idelle Labs, Ltd (128822926)

Establishment				
Name	Address	ID/FEI	Business Operations	
M.K. Packaging, Inc.		047022405	manufacture(41595-1061)	

Revised: 12/2017 Idelle Labs, Ltd