

AMMENS MEDICATED POWDER ORIGINAL- 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 - ORIGINAL

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

Questions?

call to 1-800-487-7273

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PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

AMMENS®

NEW 100% TALC FREE

TRUSTED FOR MORE THAN 100 YEARS

MEDICATED POWDER

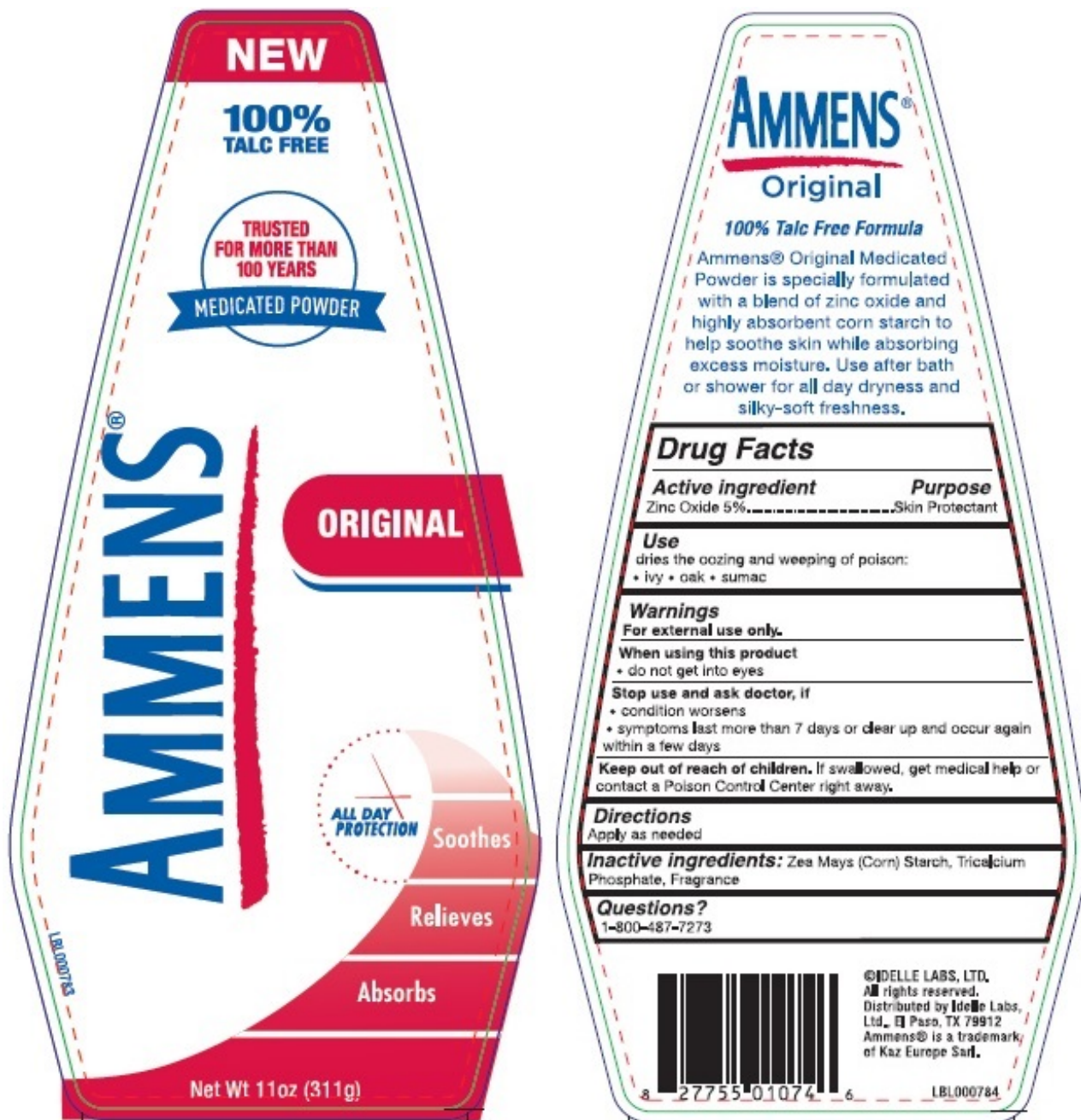
ORIGINAL

Soothes

Relieves

Absorbs

Net Wt 11oz (311g)



AMMENS MEDICATED POWDER ORIGINAL

zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41595-1060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients				
Ingredient Name				Strength
STARCH, CORN (UNII: O8232NY3SJ)				
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41595-1060-1	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(41595-1060)

Revised: 12/2017

Idelle Labs, Ltd