

PINXAV DAIPER RASH- zinc oxide ointment
Emjay Laboratories 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.

PINXAV DAIPER RASH OINTMENT

Drug Facts

Active ingredient

Zinc oxide 30%

Purpose

Skin Protectant

Uses

- helps treat and prevent diaper rash. Protects chafed skin due to diaper rash and helps seal out wetness.
- dries the oozing and weeping of poison ivy, poison oak and 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 does not improve within 7 days

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

- apply liberally as often as necessary

For diaper rash:

- change wet or soiled diapers promptly
- cleanse the diaper area and allow to dry
- apply ointment liberally, as often as necessary, with each diaper change and especially at bedtime or anytime when exposure to wet diapers may be prolonged

Inactive ingredients

Aloe Vera Gel, Aluminum Hydroxide, Cetyl Alcohol, Clove Leaf Oil, Eucayptol, Lanolin,

Menthol, Methyl Salicylate, Petrolatum, Red Ferric Oxide, Stearic Acid, Tocopherol

Questions or comments?

Call **1-888-4-PINXAV** or visit us at **www.pinxav.com**

Store at room temperature 15° - 30°C (59° - 86°F).

Principal Display Panel – Jar Label

PINXAV NDC
SKIN PROTECTANT

- helping to Soothe ,Heal and prevent Diaper rash

Net Wt 16 OZ (454 g)

The image shows the principal display panel for a 16 oz jar of PINXAV Diaper Rash Ointment. The label is divided into several sections:

- Drug Facts:** Active ingredient: Zinc Oxide 30%. Purpose: Skin protectant. Warnings: For external use only. Directions: Apply liberally as often as necessary. Other information: Store at controlled room temperature. Inactive ingredients: Zinc Stearate, Titanium Dioxide, Cetyl Alcohol, Clove Leaf Oil, Cetylalcol, Lanolin, Menthol, Methyl Salicylate, Petrolatum, Red Ferric Oxide, Stearic Acid, Tocopherol.
- Text:** "Can also be used as first aid for minor scrapes, burns, cuts, sunburn and other skin irritations."
- Central Panel:** "PEDIATRICIAN & PHARMACIST RECOMMENDED SINCE 1927", "PINK-SALVE™ DIAPER RASH OINTMENT", "CONTAINS ZINC OXIDE AND SOOTHING EMOLLIENTS SUCH AS CLOVE LEAF OIL, ALOE VERA, VITAMIN E AND LANOLIN", "NET WT. 16 oz (454 g)".
- Right Side:** Recycle symbol, "If for any reason you are not satisfied with your purchase, simply return the product with proof of purchase, for a replacement or refund. Questions? Please call toll-free 1-888-4-PINXAV or visit us at www.pinxav.com", "Distributed by Engay Labs, Inc., Cleveland, OH", "Engay Labs is committed to children's health and well-being.", Barcode, and "PINK EXP. 1/1/17".

Principal Display Panel - 4.0 OZ Tube

PINXAV DIAPER RASH Ointment

Skin protectant Zinc Oxide 30%

Help Soothe & Protect Chafed Skin

NET WT 4.0 OZ (113.4g)



Principal Display Panel - 4.0 OZ Carton

PINXAV DIAPER RASH Ointment

Skin protectant Zinc Oxide 30%

Help Soothe & Protect Chafed Skin

NET WT 4.0 OZ (113.4 g)



PINXAV DAIPER RASH

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82778-342
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	300 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
LANOLIN (UNII: 7EV65EAW6H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
EUCALYPTOL (UNII: RV6J6604TK)	
CLOVE LEAF OIL (UNII: VCA5491KVF)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MENTHOL (UNII: L7T10EIP3A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82778-342-04	1 in 1 CARTON	03/30/2004	
1		113.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:82778-342-16	454 g in 1 JAR; Type 0: Not a Combination Product	03/30/2004	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/30/2004	

Labeler - Emjay Laboratories Inc. (152870056)