

**LEUDINE ANTI-DANDRUFF- pyrithione zinc shampoo**  
**B&R Products 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.*

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**L'Eudine Anti-dandruff Shampoo**

**Active ingredient**

Pyrithione Zinc 1%

**Purpose**

Anti-dandruff

**Keep Out of Reach of Children**

If swallowed, get medical help or contact a Poison Control Center right away.

**Uses**

for relief of flaking and itching due to dandruff, and to help prevent their recurrence.

**Warnings**

**For external use only.**

**When using this product**

- avoid contact with eyes
- if contact occurs, rinse eyes thoroughly with water

**Stop use and ask a doctor if**

- condition worsens or does not improve after regular use of this product.

**Directions**

- for maximum dandruff control, use every time you shampoo
- wet hair, massage onto scalp, rinse, repeat if desired
- for best results use at least twice a week or as directed by a doctor.

**Inactive ingredients**

Acrylates Copolymer, Ammonium Laureth Sulfate, Ammonium Lauryl Sulfate, Ammonium Xylenesulfonate, Citric Acid, Cocamide MEA, Cocamidopropyl PG-Dimonium Chloride, Fragrance, Glycol Distearate, Guar Hydroxypropyltrimonium Chloride, Methylchloroisoithiazolinone, Methyloisoithiazolinone, Panthenol, Sodium Chloride, Triethanolamine, Water, Blue 1.

**Questions?**

1-800-944-5846

**Package/Label Principal Display Panel**

L'EUDINE

anti-dandruff Shampoo

2.0 fl. oz. (60 mL)

MADE IN USA

**Bottle Label**

**LEUDINE ANTI-DANDRUFF**

pyrithione zinc shampoo

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76482-013
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	1 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
ETHYL ACRYLATE AND METHYL METHACRYLATE COPOLYMER (2:1; 600000 MW) (UNII: XRK36F13ZZ)	
AMMONIUM LAURETH-2 SULFATE (UNII: 698O4Z48G6)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
AMMONIUM XYLENESULFONATE (UNII: 4FZY6L6XCM)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CO CO MONOETHANOLAMIDE (UNII: C80684146D)	
CO CAMIDO PROPYL PG-DIMONIUM CHLORIDE (UNII: 205Z54J075)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PANTHENOL (UNII: WV9CM0O67Z)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76482-013-02	60 mL in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	04/01/2013	

**Labeler** - B&R Products Inc (085560514)

**Registrant** - B&R Products Inc (085560514)

## Establishment

Name	Address	ID/FEI	Business Operations
B&R Products Inc		085560514	MANUFACTURE(76482-013)