

**LEADER MEDICATED LIP BALM- petrolatum stick**  
**Cardinal Health (Leader)**

*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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**Drug Facts**

**Active ingredient**

Petrolatum

**Purpose**

Skin Protectant

**Keep Out of Reach of Children**

If swallowed, contact a Poison Control Center.

**Uses**

Helps prevent and temporarily protects chapped or wind burned lips.

**Warnings**

For external use only. When using this product: avoid contact with eyes. Rinse with water to remove. Stop use and ask a doctor if: rash or irritation develops and lasts for more than 7 days.

**Directions**

Apply liberally and evenly as needed. Reapply as needed. Children under 2 years of age; ask a doctor before use.

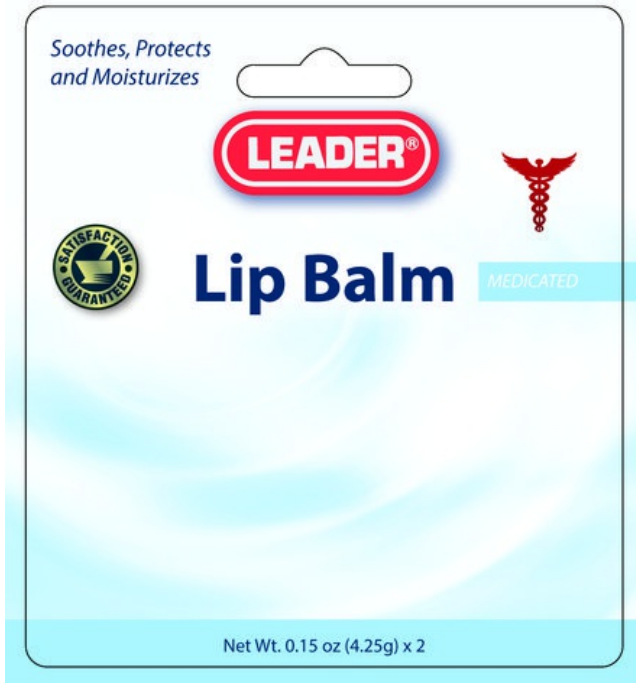
**Inactive Ingredients**

Beeswax, Camphor, Cetyl Alcohol, Flavor, Isopropyl Myristate, Lanolin, Menthol, Methylparaben, Mineral Oil, Octyldodecanol, Oleyl Alcohol, Ozokerite, Phenol, Phenyl Trimethicone, Propylparaben, Stearyl Alcohol, Water.

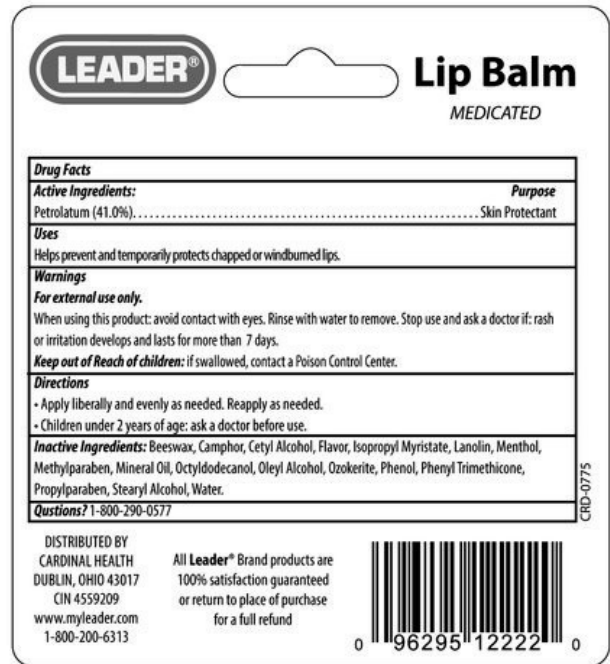
**Package/Label Principal Display Panel**

Front of Card

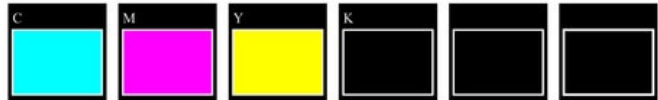
3.5in x 3.875in



Back of Card



## Imprint Color(s)



## Art Guidelines

### 1. Labels

- a. Positive imprint - 5 pt minimum ..... Sample Text
- b. Reverse imprint - 7 pt minimum ..... Sample Text
- c. Serif and italic types - 7 pt minimum ..... Sample Text
- d. Line weight, positive lines - .5 .....
- e. Line weight, reverse lines (gap) - .75 .....

- \* Ornate and display type faces will be printed on a case-by-case analysis.
- \* Registered marks and trademarks should be enlarged for clear printing.

## Color Variance Notification

- This PDF file is being viewed on an RGB monitor therefore there will be a variance between the color on your screen and the color of the actual finished product.
- This proof should be used to inspect the layout, spelling, color selection and approximate color appearance.
- Colors printed on different mediums (ie: leash and label) will not be an exact match.
- This proof is not an exact match of the finished product color or quality of the printed piece.

## LEADER MEDICATED LIP BALM

petrolatum stick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49781-112
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	41 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CERESIN (UNII: Q1LS2UJO3A)	16 mg in 1 g
YELLOW WAX (UNII: 2ZA36H0S2V)	6 mg in 1 g
OLEYL ALCOHOL (UNII: 172F2WN8DV)	6 mg in 1 g
OCTYLDODECANOL (UNII: 461N1O614Y)	9 mg in 1 g
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	5 mg in 1 g
LANOLIN (UNII: 7EV65EAW6H)	4 mg in 1 g
CETYL ALCOHOL (UNII: 936JST6JCN)	3 mg in 1 g
LIGHT MINERAL OIL (UNII: N6K5787QVP)	3 mg in 1 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	1 mg in 1 g
MENTHOL (UNII: L7T10EIP3A)	.6 mg in 1 g

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49781-112-35	1 g in 1 CONTAINER		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/01/2013	

**Labeler** - Cardinal Health (Leader) (097537435)**Registrant** - Cardinal Health (Leader) (097537435)**Establishment**

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(49781-112) , LABEL(49781-112)

Revised: 4/2014

Cardinal Health (Leader)