# BREATHE DEEPLY- menthol rub cream Kelada Creative Group

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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#### **Breathe Deeply**

#### Menthol 10%

Eucalyptus oil .25%

- When applied to chest and throat, temporarily relieves cough and congestions due to minor throat and bronchial irritation associated with the common cold, asthma, or bronchitis
- Temporarily relieves itching and discomfort associated with irritation, inflammation, and rashes due to insect bites, stings, poison ivy, oak and sumac

# For external use only

# Do not use other than as directed

#### When using this product

- avoid contact with eyes and mucous membranes
- do not apply to wounds or broken skin
- do not microwave, hear or add hot water

Organic sunflower oil, Beeswax, Spanish Rosemary essential oil, Natural Vitamin E

Keep our of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

• When applied to chest and throat, temporarily relieves cough and congestions due to minor throat and bronchial irritation associated with the common cold, asthma, or bronchitis





	Color may vary. Do not use if seal is broken or missing.	Active ingredients Purpose   Menthol 10% Nasal decongestant, topical analgesic & bronchodilator   Eucalyptus oil .25% Cough suppressant   Uses Second state   In when applied to chest and throat, temporarily relieves cough and congestions due to minor throat and bronchial irritation associated with the common cold, asthma or bronchitis   In when applied to muscles, joints and temples temporarily relieves minor aches and pains   Warnings   For external use only   Do not use other than directed	NO Artificial fragrance NO Minera NO Artificial dyes NO Siliconé NO Aluminum NO Sulfates NO Phthalates NO Parabe NO Propylene glycol
$\langle$	Manufactured by SALVE Houston, Texas USA 77042 salvenaturals.com	When using this product   ■ avoid contact with eyes and mucous membranes   ■ do not apply to wounds or broken skin   ■ do not microwave, heat or add hot water   Stop use and ask a doctor if   ■ skin irritation develops ■ condition worsens or lasts more than 7 days   Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)   Directions   See important warnings under "Uses"   Other information store at less than 25°C (77°F) with lid closed tightly   Inactive ingredients   Heliantus annuus (Organic Sunflower) Oil, Beeswax, Rosmarinus officinalis (Spanish Rosemary) Essential Oil, Tocopherol (Natural Vitamin E).	13189 01823 0 SALV-BREA-302
		Questions or comments? 1-281-684-0755 salvenaturals.com	
	REATHE nthol rub cr	E <b>DEEPLY</b> ream	

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71157-0019
Route of Administration	TOPICAL		

	Active Ingredient/Active Moiety		
Ш	Ingredient Name	<b>Basis of Strength</b>	Strength
I	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	170 g in 90 mL

<b>Inactive Ingredien</b>	its			
	Ingredient Name		Strength	
SUNFLOWER OIL (UN	II: 3W1JG795YI)			
WHITE WAX (UNII: 7G1	J5DA97F)			
.ALPHATOCOPHERO	L (UNII: H4N855PNZ1)			
ROSEMARY OIL (UNII:	8LGU7VM393)			
EUCALYPTUS OIL (UN	III: 2R04ONI662)			
Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
<b>1</b> NDC:71157-0019-1	0 mL in 1 CAN; Type 0: Not a Combination Product	01/09/2017		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	0 1/0 9 /20 17		

Labeler - Kelada Creative Group (014340121)

**Registrant -** Kelada Creative Group (014340121)

Establishment					
Name	Address	ID/FEI	Business Operations		
Kelada Creative Group		0 14340 121	manufacture(71157-0019)		

Revised: 12/2018

Kelada Creative Group