

ACTIVATE JOINT AND MUSCLE RELIEF- lidocaine hydrochloride, menthol cream
Liberty Health Supply, LLC

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.

Activate Joint and Muscle Relief Cream

Drug Facts

Active Ingredients

4.00% Lidocaine HCl

1.00% Menthol

Purpose

Topical Anesthetic

Indications:

For the temporary relief of pain and itching due to minor burns, sunburn, minor cuts, scrapes, insect bites and minor skin irritations

Warnings:

- For external use only.
- Do not use in large quantities, particularly over raw or blistered areas.
- If symptoms persist for more than seven days, discontinue use and consult physician.
- Avoid contact with eyes. Rinse well if contact occurs

Keep out of reach of children.

- If swallowed, consult physician.

Directions:

- Adults and children two-years of age or older: Apply small amount to affected area not more than three to four times daily.
- Apply after shower or bath for best result
- Children under two-years of age: consult a physician

Additional information:

Store at room temperature.

Other Ingredients:

Aloe Barbadensis (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana (Arnica) Extract, Azadirachta Indica (Neem) Oil, Butyrospermum Parkii (Shea) Butter, C13-14 Isoparaffin, Calophyllum Inophyllum (Tamanu) Seed Oil, Camellia Sinensis (Green Tea) Extract, Cetearyl Alcohol, Chondroitin Sulfate, Citric Acid, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Emu Oil, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Glucosamine Sulfate, Laureth-7, Methylsulfonylmethane (MSM), Phenoxyethanol,

Polyacrylamide, Polysorbate-20, Sesamum Indicum (Sesame) Seed Oil, SD-Alcohol 40B, Stearic Acid, Tocopheryl Acetate (Vitamin E), Theobroma Cacao (Cocoa) Butter, Xanthan Gum.

Package Labeling:

Activate Pain Relief Cream is used by consumers to reduce pain and to help them return to a pain-free active lifestyle.

Activate provides maximum strength lidocaine in conjunction with other ingredients to provide fast relief!

**Fast Acting
Long Lasting
Pleasant Smell
Non-Greasy**

**Proudly Made In
The U.S.A.**



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4 fl oz / 118 ml

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Distributed by:
Unified Biologics, LLC
Westerville, OH 43021
1.800.483.8024
activatepaincream.com

ACTIVATE JOINT AND MUSCLE RELIEF

lidocaine hydrochloride, menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71868-080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength

ALOE VERA LEAF (UNII: ZY81Z83H0X)
WATER (UNII: 059QF0KO0R)
ARNICA MONTANA (UNII: O80TY208ZW)
AZADIRACHTA INDICA SEED OIL (UNII: 4DKJ9B3K2T)
SHEA BUTTER (UNII: K49155WL9Y)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
TAMANU OIL (UNII: JT3LVK84A1)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
BERGAMOT OIL (UNII: 39W1PKE3J1)
EMU OIL (UNII: 344821WD61)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
GLYCERIN (UNII: PDC6A3C0OX)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)
LAURETH-7 (UNII: Z95S6G8201)
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
SESAME OIL (UNII: QX10HYY4QV)
STEARIC ACID (UNII: 4ELV7Z65AP)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
XANTHAN GUM (UNII: TTV12P4NEE)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71868-080-01	1 in 1 BOX	11/01/2017	
1		118.294 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/01/2017	

Labeler - Liberty Health Supply, LLC (080886320)