

LEVEL SELECT MENTHOL CAMPHOR MUSCLE RUB- 10% menthol, 5% camphor muscle rub lotion lotion
Kandenwood 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.

Level Select 10% Menthol, 5% Camphor 6 ozTube

OTC-ACTIVE INGREDIENTS

Menthol 10%

Camphor 5%

OTC-PURPOSE

Topical Analgesic

Uses

Temporary relief from minor aches and pains of muscles and joints, associated with strains, sprains, arthritis, backache, bruises

Warnings

For external use only

When using this product:

- Avoid contact with eyes, mucous membranes, and genital areas.
- Do not use on irritated, broken, or damaged skin. If redness or irritation occurs, discontinue use
- If skin is sensitive, consult a physician before use
- Do not bandage the area of application
- Do not use a heating pad with this product
- Do not use in combination with other topical products
- Do not expose application site to heat or direct sunlight

Stop use and ask a doctor if:

- Condition worsens
- Symptoms continue for more than 7 days
- Symptoms clear up and then get worse
- You experience blistering, severe burning pain, or swelling at application site

If pregnant or breastfeeding:

consult a physician before use

Keep out of reach of children and pets

If accidentally ingested, please seek medical help

Directions:

Adults and Children 12 years and older:

Apply a thin layer of lotion to affected area no more than 3-4 times daily

Massage product into skin until fully absorbed

Wash hands, if used, after application with soap and water

Children under 12 years of age:

Consult a physician before use

Other Information:

Store in a cool, dry place with lid closed tightly

Inactive Ingredients:

Aesculus Hippocastanum (Horse Chestnut) Extract, Aloe Barbadensis (Aloe Vera) Leaf Juice, Beta-Caryophyllene, Blue #1, Caffeine, Caprylyl Glycol, Carbomer, Cymbopogon, Flexuosus (Lemongrass Oil), Glycerin, Methylsulfonylmethane (MSM), Oleth-3, Oleth-3 Phosphate, Phenoxyethanol, Polysorbate 80, Propanediol, Rosmarinus Officinalis (Rosemary) Extract, Sodium Hydroxide, Symphytum Officinale (Comfrey) Leaf Extract, Tetrasodium Glutamate Diacetate, Tocopheryl Acetate (Vitamin E) Triethanolamine, Water, Yellow #5

Level Select 10% Menthol, 5% Camphor 6 oz Tube Lotion



FM#

39244

DIGITAL PROOF APPROVAL CONTRACT

Kaderwood
 Customer
 A162072
 ARTWORK ID Number
 53570.ARD
 CAD Number
 CM
 Sales Rep
 L 2.50000 x W 0.00000 x D 7.00000
 Description
 12/22/2022
 Date

CUSTOMER SIGNATURE REQUIRED

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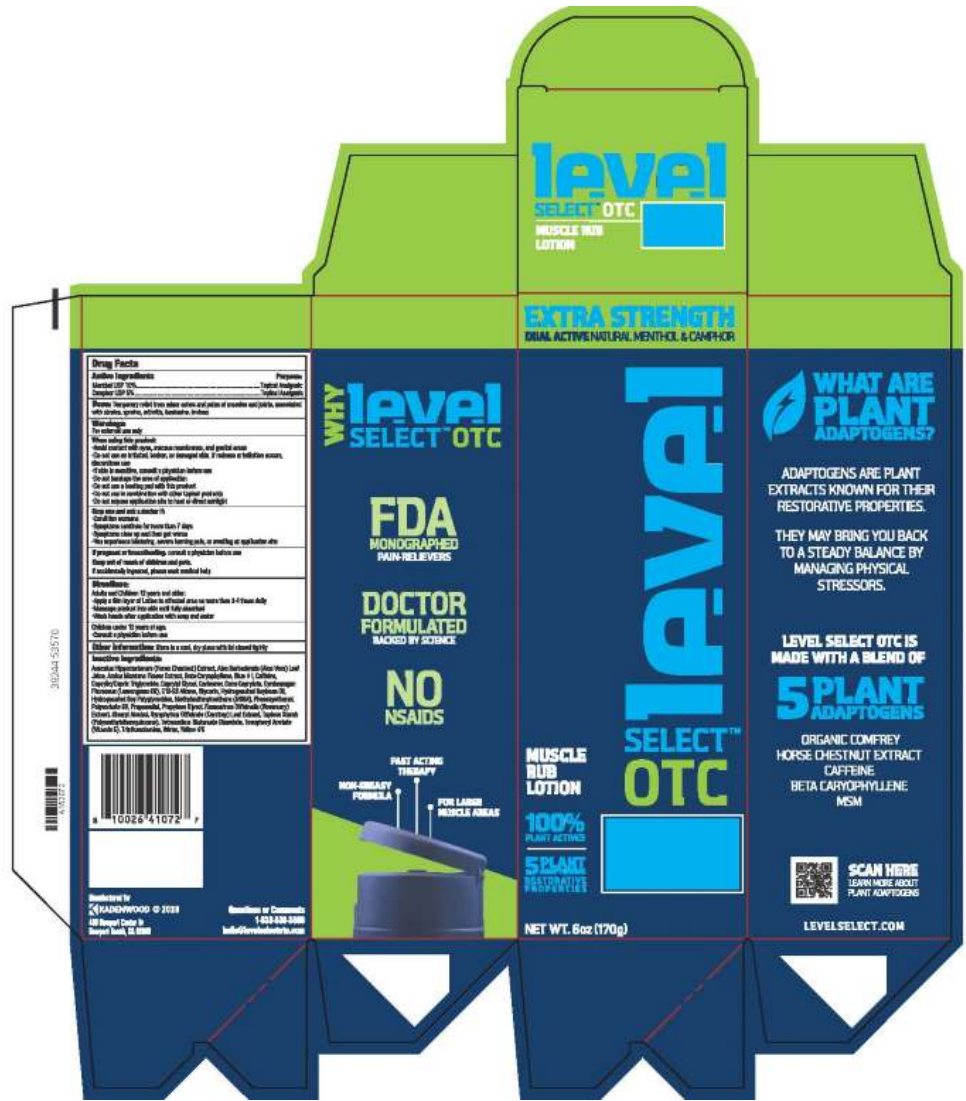
Customer Signature _____ Date _____

INKS/PANTONES/POLYMER/EMBOS

- Cyan
- Magenta
- Yellow
- Black
- Emboss
- SPOT UV
- PANTONE 305 C
- PANTONE 298 C
- PANTONE 325 C

COATINGS

AUTOMATIC FIXES WERE APPLIED TO YOUR ARTWORK
 Fonts were created to Outlines



LEVEL SELECT MENTHOL CAMPHOR MUSCLE RUB

10% menthol, 5% camphor muscle rub lotion lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83191-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength

CAPRYLIC/CAPRIC/LINOLEIC TRIGLYCERIDE (UNII: U73D397055)
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)
STARCH, TAPIOCA (UNII: 24SC3U704I)
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)
PROPANEDIOL (UNII: 5965N8W85T)
TROLAMINE (UNII: 9O3K93S3TK)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
WATER (UNII: 059QF0KO0R)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
GLYCERIN (UNII: PDC6A3C0OX)
CYMBOPOGON FLEXUOSUS LEAF (UNII: 7LJ4Y1UJG7)
CAFFEINE (UNII: 3G6A5W338E)
HORSE CHESTNUT (UNII: 3C18L6RJAZ)
ROSEMARY OIL (UNII: 8LGU7VM393)
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)
COMFREY (UNII: D05HXX6R3G)
CARYOPHYLLENE (UNII: BHW853AU9H)
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
VITAMIN E POLYETHYLENE GLYCOL SUCCINATE (UNII: O03S90U1F2)
C15-23 ALKANE (UNII: J3N6X3YK96)
COCO-CAPRYLATE (UNII: 4828G836N6)
HYDROGENATED SOYBEAN OIL (UNII: A2M91M918C)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83191-001-01	70.87 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product	02/13/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/13/2023	

Labeler - Kandenwood LLC (102301802)