

**LEVEL SELECT MENTHOL CAMPHOR PATCH- 10% menthol, 5% camphor patch patch**  
**Kadenwood 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.*

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**Level Select 10% Menthol, 5% Camphor**

**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:**

- Wash hands after applying and removing patch
- 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 applicaton 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:

Clean the area you wish to adhere the patch to.

Remove backing from the patch

Apply the patch to the cleaned and dried area.

Apply pressure to the patch for 30 seconds, pressing firmly against the skin.

Wear one patch for up to 8 hours

Repeat as necessary, but no more than 3 times daily

Children under 12 years of age:

- Consult a physician before use

**Other Information:**

Store in a cool, dry place

**Inactive Ingredients:**

MSM, Beta Caryophyllene, Horse Chestnut Extract, Organic Comfrey, Caffeine, Lemongrass Essential Oil, Rosemary Extract, Acrylic Adhesive, Polyethylene Foam

**Level Select 10% Menthol 5% Camphor Patch**



## LEVEL SELECT MENTHOL CAMPHOR PATCH

10% menthol, 5% camphor patch patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83191-004
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg in 100 mg
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	5 mg in 100 mg

### Inactive Ingredients

Ingredient Name	Strength

<b>LOW DENSITY POLYETHYLENE</b> (UNII: J245LN42AI)	
<b>CAFFEINE</b> (UNII: 3G6A5W338E)	
<b>HORSE CHESTNUT</b> (UNII: 3C18L6RJAZ)	
<b>ROSEMARY OIL</b> (UNII: 8LGU7VM393)	
<b>EAST INDIAN LEMONGRASS OIL</b> (UNII: UP0M8M3VZW)	
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)	
<b>COMFREY</b> (UNII: D05HXK6R3G)	
<b>CARYOPHYLLENE</b> (UNII: BHW853AU9H)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83191-004-04	255 mg in 1 BOX; Type 0: Not a Combination Product	01/19/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/19/2023	

**Labeler** - Kadenwood LLC (102301802)

**Registrant** - Akron Coating & Adhesives (186569323)

### Establishment

Name	Address	ID/FEI	Business Operations
Akron Coating & Adhesives		186569323	manufacture(83191-004)

Revised: 3/2023

Kadenwood LLC