#### 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 applicaton site

## If pregnant or breastfeeding:

consult a physician before use

# Keep out of reach of chlidren 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

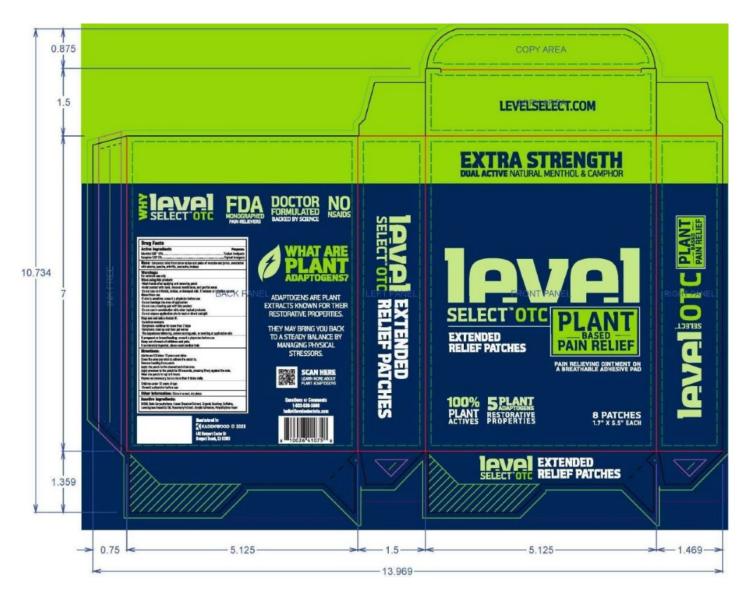
# **Other Information:**

Store in a cool, dry place

## Inactive Ingredients:

MSM, Beta Caryophylene, 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								
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:83191-004				
Route of Administration	TOPICAL							
Active Ingredient/Active	F	Ctwo w w th						
Ingredient Name Strength					Strength			
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) MENTHOL					10 mg in 100 mg			
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - CAMPHOR (SYNTHETIC) - CAMPHOR (SYNTHETIC)				5 mg in 100 mg				
Inactive Ingredients								
Ingredient Name					Strength			

CAFFEINE (UNII: 3G6	5A5W338F)					
HORSE CHESTNUT	,					
ROSEMARY OIL (UN	. ,					
-	NGRASS OIL (UNII: UPOM8M3VZW)					
	<b>E</b> (UNII: 9H4PO4Z4FT)					
COMFREY (UNII: D05HXK6R3G)						
CARYOPHYLLENE (UNII: BHW853AU9H)						
Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
	255 mg in 1 BOX; Type 0: Not a Combination Product	01/19/2023				
		01/19/2023				
		01/19/2023				
	Product	01/19/2023				
04	Product	01/19/2023 Marketing Start Date	Marketing End Date			

Labeler - Kadenwood LLC (102301802)

Registrant - Akron Coating & Adhesives (186569323)

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

Revised: 3/2023

Kadenwood LLC