

**AWAYE- capsaicin cream**  
**Lumiera Health Inc.**

*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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**Active ingredient**

Capsaicin 0.025%

**Purpose**

Topical analgesic

**Uses**

Temporarily relieves aches and pains of muscles and joints associated with: simple backache – lumbago – strains – sprains - arthritis

**Warning**

**For external use only**

**Flammable:** Keep away from fire or flame and heated surfaces.

**Do not use** – if you are allergic to any ingredient in this product - on open wounds, damaged, broken or irritated skin - with external heat, such as an electric heating pad or a TENS device.

**When using this product - Use only as directed** - Avoid contact with the eyes or mucus membranes - Do not tightly bandage - Do not inhale.

**Stop use and ask a doctor if** – condition worsens – headache, rash, itching, erythema, redness, burning discomfort or excessive irritation of the skin develops - symptoms persist for more than 7 days – symptoms clear up and occur again within a few days.

**If pregnant or breastfeeding,** ask a healthcare professional before use.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

**Direction**

Apply 2 pumps to affected area no more than 3-4 times a day - Rub in well until absorbed by the skin - wash hands thoroughly after use with cold water - May take up to 2 weeks for a greater effect.

**Inactive ingredient**

B-Caryophyllene, Benzyl Alcohol, Cetyl Alcohol, Glyceryl Stearate, C13-14 Isoparaffin, Laureth-7, Oleic Acid, PEG100 Stearate, Polyacrylamide, Polysorbate 80, Potassium Sorbate, Purified Water, Xantham Gum.

**Other information**

Store in a cool dry place away from direct sunlight – Store with cap closed tightly – Do not use if seal is broken.

**Product label**

NDC 00000-000-00 Peel Back Here ▶

**The new generation of pain relief**

For temporary relief of aches and pains due to:

- Simple Backache - Arthritis
- Lumbago - Muscle Pain
- Sprains & Strains - Joint Pain

Distributed by Lumiera Health Inc.  
St-Hubert, Quebec J3Y 8K5 Canada  
awayerelief.com 1-866-722-2442  
Made in Canada



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**awaye**<sup>™</sup>

**PAIN RELIEF CREAM**

WITH CAPSAICIN AND B-CARYOPHYLLENE

**CLINICALLY TESTED**

Net Wt 1.6 oz (45 g)

**Drug Facts**

Active ingredient:	Purpose
Capsaicin 0.025% .....	Topical analgesic

**Uses**

Temporarily relieves aches and pains of muscles and joints associated with:

- simple backache ■ lumbago ■ strains
- sprains ■ arthritis

**Warnings**

For external use only

Do not use ■ if you are allergic to any ingredient in this product ■ on open wounds, damaged, broken or irritated skin ■ with external heat, such as an electric heating pad or a TENS device.

When using this product ■ Use only as directed ■ Avoid contact with the eyes or mucus membranes ■ Do not tightly bandage ■ Do not inhale.

▶

### **Drug Facts** (continued)

Stop use and ask a doctor if ■ condition worsens ■ headache, rash, itching, erythema, redness, burning discomfort or excessive irritation of the skin develops ■ symptoms persist for more than 7 days ■ symptoms clear up and occur again within a few days.

If pregnant or breastfeeding, ask a healthcare professional before use.

Keep out of reach of children ■ If swallowed, get medical help or contact a Poison Control Center immediately.

### **Directions**

Adults: Apply 2 pumps to affected area no more than 3-4 times a day ■ Rub in well until absorbed by the skin ■ Wash hands thoroughly after use with cold water ■ May take up to 2 weeks for a greater effect.

### **Other information**

Store in a cool dry place away from direct sunlight ■ Store with cap closed tightly ■ Do not use if seal is broken.

### **Inactive ingredients**

B-Caryophyllene, Benzyl Alcohol, Cetyl Alcohol, Glyceryl Stearate, C13-14 Isoparaffin, Laureth-7, Oleic Acid, PEG100 Stearate, Polyacrylamide, Polysorbate 80, Potassium Sorbate, Purified Water, Xantham Gum.

## **AWAYE**

capsaicin cream

### **Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82531-001
<b>Route of Administration</b>	TOPICAL		

### **Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>CAPSAICIN</b> (UNII: S07O44R1Z M) (CAPSAICIN - UNII:S07O44R1Z M)	CAPSAICIN	0.025 g in 100 g

### **Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>CARYOPHYLLENE</b> (UNII: BHW853AU9H)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>C13-14 ISOPARAFFIN</b> (UNII: E4F12ROE70)	
<b>LAURETH-7</b> (UNII: Z95S6G8201)	
<b>OLEIC ACID</b> (UNII: 2UMI9U37CP)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	

<b>POLYACRYLAMIDE (1500 MW)</b> (UNII: 5D6TC4BRWW)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82531-001-01	45 g in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/07/2022	

**Labeler** - Lumiera Health Inc. (208214151)

Revised: 2/2022

Lumiera Health Inc.