

**ALEVEX- camphor and menthol spray**  
**Bayer HealthCare 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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**Aleve X Dry Spray UI1614336**

**Drug Facts**

**Active ingredients**

*(To Deliver)*

Camphor 5.5%

Menthol 16%

**Purpose**

Pain Relieving Spray

For the temporary relief of minor aches and pains of muscles and joints associated with:

- arthritis
- simple backache
- strains
- sprains
- bruises

Provides penetrating pain relief

**Warnings**

**For external use only**

**Flammable:** do not use near heat, flame, or while smoking.

**Do not use**

- if you have ever had an allergic reaction to this product or any of its ingredients

**When using this product**

- avoid contact with the eyes and mucous membranes
- use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal
- contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F
- do not bandage tightly
- do not use with a heating pad, medicated patch or other types of local heat
- do not apply to wounds or damaged, broken or irritated skin

## Stop use and ask a doctor if

- condition worsens or irritation develops
- pain, swelling or blistering develops where product was applied
- redness or severe burning develops where product was applied
- symptoms persist for more than 7 days or clear up and occur again within a few days

**If pregnant or breast-feeding**, ask a health professional before use.

If swallowed, get medical help or contact a Poison Control Center right away.

## Directions

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Adults and children 12 years of age and older	<ul style="list-style-type: none"><li>• Shake well before use</li><li>• Apply to affected area not more than 3 to 4 times daily</li><li>• Do not apply to face</li><li>• Use in a well-ventilated area and avoid inhalation</li><li>• Wash hands with soap and water after use if product comes in contact with hands</li></ul>
Children under 12 years of age	<ul style="list-style-type: none"><li>• Ask a doctor</li></ul>

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## Other information

- store between 20°-25°C (68°-77°F)

## Inactive ingredients

boswellia carterii oil, clove oil, dimethylaminoethyl methacrylate copolymer, dimethyl isosorbide, eucalyptus oil, fragrance, isobutane, isopentane, isopulegol, linseed oil, menthoxypropanediol, peppermint oil, propane, propanediol, rosemary oil, SD alcohol 40-B (13% v/v), thymus mastichina flower oil, tocopherol, vanillyl butyl ether, vinyl caprolactam, vinylpyrrolidone

## Questions

**1-800-395-0689**

## Package label display

ALEVEX™

PAIN RELIEVING

SPRAY

**MAX**

**STRENGTH**

**MENTHOL  
COOLS IN  
SECONDS**  
FOR EXTERNAL  
USE ONLY  
NET WT 3.2 OZ (91 g)

**NEW!**  
**DIFFERENT INGREDIENTS**  
**MENTHOL + CAMPHOR**


**ALEVEX™**  
**PAIN RELIEVING  
SPRAY**

**MAX  
STRENGTH  
MENTHOL**

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<b>Uses</b> For the temporary relief of minor aches and pains of muscles and joints associated with: <input type="checkbox"/> arthritis <input type="checkbox"/> simple backache <input type="checkbox"/> strains <input type="checkbox"/> sprains <input type="checkbox"/> bruises		<b>Directions</b> Adults and children 12 years of age and older	
<b>Warnings</b> <b>For external use only</b> <b>Flammable:</b> do not use near heat, flame, or while smoking. <b>Do not use</b> <input type="checkbox"/> if you have ever had an allergic reaction to this product or any of its ingredients		<input type="checkbox"/> Shake well before use <input type="checkbox"/> Apply to affected area not more than 3 to 4 times daily <input type="checkbox"/> Do not apply to face <input type="checkbox"/> Use in a well-ventilated area and avoid inhalation <input type="checkbox"/> Wash hands with soap and water after use if product comes in contact with hands <input type="checkbox"/> Ask a doctor	
<b>When using this product</b> <input type="checkbox"/> avoid contact with the eyes and mucous membranes <input type="checkbox"/> use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal <input type="checkbox"/> contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F <input type="checkbox"/> do not bandage tightly <input type="checkbox"/> do not use with a heating pad, medicated patch or other types of local heat <input type="checkbox"/> do not apply to wounds or damaged, broken or irritated skin		<b>Other information</b> store between 20° – 25° C (68° – 77°F)	
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**ALEVEX**  
camphor and menthol spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0280-0049
<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 1 g
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	5.5 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>ISOBUTANE</b> (UNII: BXR49TP611)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>FRANKINCENSE OIL</b> (UNII: 67ZYA5T02K)	
<b>DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER</b> (UNII: 905HNO1SIH)	
<b>LINSEED OIL</b> (UNII: 84XB4DV00W)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>3-((L-MENTHYL)OXY)PROPANE-1,2-DIOL</b> (UNII: KD6TZ2Q1CH)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>ROSEMARY OIL</b> (UNII: 8LGU7VM393)	
<b>ISOPENTANE</b> (UNII: ZH67814I0O)	
<b>VANILLYL BUTYL ETHER</b> (UNII: S2ULN37C9R)	
<b>N-VINYLCAPROLACTAM</b> (UNII: KFC10CY9UP)	
<b>THYMUS MASTICHINA FLOWERING TOP OIL</b> (UNII: 9NP0832457)	
<b>ISOPULEGOL</b> (UNII: 3TH92O3BXN)	
<b>N-VINYLPYRROLIDINONE</b> (UNII: 76H9G81541)	
<b>CLOVE OIL</b> (UNII: 578389D6D0)	
<b>DIMETHYL ISOSORBIDE</b> (UNII: SA6A6V432S)	
<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)	
<b>PROPANE</b> (UNII: T75W9911L6)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0049-01	91 g in 1 CAN; Type 0: Not a Combination Product	04/01/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/01/2021	

**Labeler** - Bayer HealthCare LLC (112117283)