

**ALEVEX- camphor and menthol spray**  
**Bayer HealthCare LLC**

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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

- Shake well before use
- Apply to affected area not more than 3 to 4 times daily
- Do not apply to face
- Use in a well-ventilated area and avoid inhalation
- Wash hands with soap and water after use if product comes in contact with hands

Children under 12 years of age

- Ask a doctor
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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



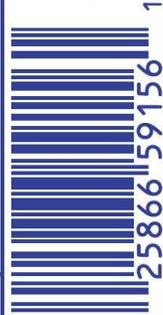
**MAX STRENGTH MENTHOL**

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<p><b>Drug Facts</b></p> <p><b>Active ingredients</b> (To Deliver) Camphor 5.5%.....Pain Relieving Spray Menthol 16%.....Pain Relieving Spray</p> <p><b>Purpose</b></p> <p><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</p> <p>Provides penetrating pain relief</p> <p><b>Warnings</b> For external use only</p> <p><b>Flammable:</b> do not use near heat, flame, or while smoking.</p> <p><b>Do not use</b>  <input type="checkbox"/> if you have ever had an allergic reaction to this product or any of its ingredients</p> <p><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</p> <p><b>Stop use and ask a doctor if</b>  <input type="checkbox"/> condition worsens or irritation develops  <input type="checkbox"/> pain, swelling or blistering develops where product was applied  <input type="checkbox"/> redness or severe burning develops where product was applied  <input type="checkbox"/> symptoms persist for more than 7 days or clear up and occur again within a few days</p>	<p><b>Drug Facts (continued)</b></p> <p>If pregnant or breast-feeding, ask a health professional before use. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <table style="width: 100%; border: none;"> <tr> <td style="border: none; width: 50%;">Adults and children 12 years of age and older</td> <td style="border: none; width: 50%;"> <input type="checkbox"/> Shake well before use  <input type="checkbox"/> Apply to affected area not more than 3 to 4 times daily                 </td> </tr> <tr> <td style="border: none;">Children under 12 years of age</td> <td style="border: none;"> <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                 </td> </tr> </table> <p><b>Other information</b> store between 20° – 25° C (68° – 77°F)</p> <p><b>Inactive ingredients</b> 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</p> <p><b>Questions? 1-800-395-0689</b></p>	Adults and children 12 years of age and older	<input type="checkbox"/> Shake well before use <input type="checkbox"/> Apply to affected area not more than 3 to 4 times daily	Children under 12 years of age	<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
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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>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	5.5 mg in 1 g
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	16 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>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>ROSEMARY OIL</b> (UNII: 8LGU7VM393)	
<b>PROPANE</b> (UNII: T75W9911L6)	
<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: ROZB2556P8)	
<b>3-((L-MENTHYL)OXY)PROPANE-1,2-DIOL</b> (UNII: KD6TZ2QICH)	
<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)	

## 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 Drug	M017	04/01/2021	

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