

ALEVEX- camphor and menthol spray
Bayer HealthCare LLC

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

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
-

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)

<p>Drug Facts</p> <p>Active ingredients (To Deliver) Camphor 5.5%.....Pain Relieving Spray Menthol 16%.....Pain Relieving Spray</p> <p>Purpose</p> <p>Uses 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>Warnings For external use only Flammable: do not use near heat, flame, or while smoking. Do not use <input type="checkbox"/> if you have ever had an allergic reaction to this product or any of its ingredients</p> <p>When using this product <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>Stop use and ask a doctor if <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>Drug Facts (continued) If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions 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</p> <p><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</p> <p>Children under 12 years of age <input type="checkbox"/> Ask a doctor</p> <p>Other information store between 20° – 25° C (68° – 77°F)</p> <p>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</p> <p>Questions? 1-800-395-0689</p>
---	---

Bayer and the Bayer Cross are registered trademarks of Bayer. Alevex is a trademark of Bayer. ©2020 Bayer.
 Pat.: patents.livewell.bayer.com Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981 C00010064 DOT 2P M5706 Bayer

ALEVEX		
camphor and menthol spray		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:0280-0049
Route of Administration	TOPICAL	
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	5.5 mg in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	16 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ISOBUTANE (UNII: BXR49TP611)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
ALCOHOL (UNII: 3K9958V90M)	
PROPANEDIOL (UNII: 5965N8W85T)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
PROPANE (UNII: T75W9911L6)	
FRANKINCENSE OIL (UNII: 67ZYA5T02K)	
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	
LINSEED OIL (UNII: 84XB4DV00W)	
TOCOPHEROL (UNII: ROZB2556P8)	
3-((L-MENTHYL)OXY)PROPANE-1,2-DIOL (UNII: KD6TZ2QICH)	
ISOPENTANE (UNII: ZH67814I0O)	
VANILLYL BUTYL ETHER (UNII: S2ULN37C9R)	
N-VINYLCAPROLACTAM (UNII: KFC10CY9UP)	
THYMUS MASTICHINA FLOWERING TOP OIL (UNII: 9NP0832457)	
ISOPULEGOL (UNII: 3TH92O3BXN)	
N-VINYLPYRROLIDINONE (UNII: 76H9G81541)	
CLOVE OIL (UNII: 578389D6D0)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
EUCALYPTUS OIL (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)