

LEADER CAMPHOR SPIRIT- camphor (natural) liquid
Cardinal Health, 110 dba Leader

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.

LEADER Camphor Spirit (New NDC)

(Dillute with 3 parts olive oil and mix well)

Adults and children 2 yrs. and older apply to the affected area not more than 3 or 4 times daily.

Children under 2 yrs. of age: consult a doctor before use.

Alcohol 84%, Purified Water

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center right away. In case of eye contact, flush eyes with running water for 15 minutes, get medical attention.

External Analgesic

For external use only.

Do not drink. If swallowed, immediately give 3 or 4 glasses of water. Do not induce vomiting. If vomiting occurs, give fluids again. Do not give anything by mouth to an unconscious or convulsing person. Get medical attention immediately.

Avoid contact with eyes or mucous membranes.

Do not apply to irritated skin.

For the temporary relief of minor aches, muscle and joint pain associated with arthritis, strains, bruises and simple backache

Camphor 10%

Drug Facts Active ingredients Camphor 10%..... Purpose External analgesic Indications ■ for the temporary relief of minor aches and pains of muscles and joints associated with arthritis, strains, bruises and simple backache. Warnings For external use only. ■ Do not drink. If swallowed, immediately give 3 or 4 glasses of water. Do not induce vomiting. If vomiting occurs, give fluids again. Do not give anything by mouth to an unconscious or convulsing person. Get medical attention immediately. ■ Avoid contact with eyes or mucous membranes. ■ Do not apply to irritated skin. ■ Do not use undiluted product. When using this product do not bandage tightly. Discontinue use and consult a doctor if ■ condition worsens, or if excessive irritation develops. <i>Continued</i>	LEADER NDC 70000-0396-1 Camphor Spirit USP Alcohol 84% External Analgesic 100% Money Back Guarantee DANGER POISON 2 FL OZ (59 mL)	Drug Facts (continued) ■ symptoms persist for more than 7 days, or clear up and occur again within a few days. Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center (1-800-222-1222) right away. In case of eye contact, flush eyes with running water for 15 minutes, get medical attention. Directions (Dilute with 3 parts olive oil and mix well) ■ Adults and children 2 yrs. and older: apply to the affected area not more than 3 or 4 times daily. ■ Children under 2 yrs. of age: consult a doctor before use. Other information ■ Flammable: Keep away from spark, heat and flame. Inactive ingredients Alcohol 84%, Purified Water. Questions or Comments? 1-800-662-3435	CIN 5455787 REV. 12/18 FPO 96295 13508 DISTRIBUTED BY CARDINAL HEALTH DUBLIN, OHIO 43007 www.mylender.com 1-800-200-6535 © 2018 CARDINAL HEALTH 0 4
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LEADER CAMPHOR SPIRIT

camphor (natural) liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0396
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0396-1	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/17/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/17/2018	

Labeler - Cardinal Health, 110 dba Leader (063997360)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(70000-0396) , analysis(70000-0396) , pack(70000-0396) , label(70000-0396)