

**PROFLEXA- camphor cream**  
**Sinoveda Canada 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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**Proflexa**

**Active ingredient**

Camphor 3.3%

**Purpose**

Camphor 3.3%.....Topical Analgesic

**Uses**

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

- Simple Backache
- Arthritis
- Strains
- Bruises
- Sprains

**Warnings**

**For external use only**

**When using this product**

- Avoid contact with eyes
- Do not apply to wounds or damaged skin
- Do not bandage tightly

**Stop use and ask doctor if**

- Condition worsens
- Irritation occurs
- Symptoms persist for more than 7 days or clear up and occur again within a few days

**If pregnant or breastfeeding,** 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.

## **Directions**

**Adults and children 2 years of age and older:** Apply to affected area not more than 3 to 4 times daily

**Children under 2 years of age:** Consult a doctor

## **Other information**

Store in a cool, dry place away from light

## **Inactive ingredients**

Angelica Polymorpha Sinensis Root Extract, Boswellia Sacra (Frankincense) Gum/Resin Extract, Butyrospermum Parkii (Shea) Butter, Caprylic/Capric Triglyceride, Carthamus Tinctorius (Safflower) Flower Extract, Cetearyl Oliviate, Citrus Paradisi (Grapefruit) Seed Extract, Commiphora Myrrha Resin Extract, Eugenia Caryophyllus (Clove) Flower Oil, Glycerin, Glyceryl Stearate Citrate, Isopropyl Palmitate, Ligusticum Chuanxiong Root Extract, Sodium Benzoate, Sodium Hyaluronate, Stearyl Alcohol, Vitis Vinifera (Grape) Seed Oil, Xanthan Gum

## **Questions or comments?**

1-780-466-0086 Mon-Fri 9am-5pm MST

954-414-0380

Proflexa

Botanical Pain Relief Cream for Muscles and Joints

Camphor 3.3%

NDC #: 83011-001-01

Radiate Freedom

Net Wt 1.76 oz (50g)



NDC #: 8301 1-001-01

# PROFLEXA<sup>®</sup>

## RADIATE FREEDOM

**BOTANICAL PAIN RELIEF CREAM FOR MUSCLES AND JOINTS**

**Camphor 3.3%**

**NETWT 1.76 OZ (50g)**

**DRUG FACTS:** Active Ingredient: Camphor 3.3%. Purpose: Topical Analgesic.

**USES:** For the temporary relief of the minor aches and pains of muscles and joints associated with:  
• Simple Backache • Arthritis • Strains • Bruises • Sprains

**WARNINGS:** For external use only.

**WHEN USING THE PRODUCT:**

- Avoid contact with eyes.
- Do not apply to wounds or damage skin.
- Do not bandage tightly.

**STOP USE AND ASK DOCTOR IF:** Condition worsens. Irritation occurs. Symptoms persist for more than 7 days or clear up and occur again within a few days. If pregnant or breastfeeding, ask a health professional before use.

**KEEP OUT OF THE REACH OF CHILDREN:** If swallowed, get medical help or contact a Poison Control Center right away.

**DIRECTIONS:** Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. **CHILDREN UNDER 2 YEARS OF AGE:** consult a doctor.

**OTHER INFORMATION:** Store in a cool, dry place away from light.

**INACTIVE INGREDIENTS:**

Angelica Polymorpha Sinensis Root Extract, Boswellia Sacra (Frankincense) Gum/Resin Extract, Butyrospermum Parkii (Shea) Butter, Caprylic/Capric Triglyceride, Carthamus Tinctorius (Safflower) Flower Extract, Cetearyl Olivate, Citrus Paradisi (Grapefruit) Seed Extract, Commiphora Myrrha Resin Extract, Eugenia Caryophyllus (Clove) Flower Oil, Glycerin, Glyceryl Stearate Citrate, Isopropyl Palmitate, Ligusticum Sibiricum Root Extract, Sodium Benzoate, Sodium Hyaluronate, Stearyl Alcohol, Vitis Vinifera (Grape) Seed Oil, Xanthan Gum

**Manufactured for:**

Sinoveda Canada Inc.,  
Edmonton, AB T6E 5V2  
Questions/Comments:  
1-780-466-0096

**USA Distributor:**

TruLife Distribution  
401 E. Las Olas Blvd Suite 1400  
Fort Lauderdale, Florida USA 33301  
954-414-0380



**MADE IN CANADA**

# PROFLEXA<sup>®</sup>

## Topical Pain Relief Cream

### Drug Facts

**Active ingredient**

Camphor 3.3%.....

**Purpose**

Topical Analgesic

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

- Simple Backache
- Arthritis
- Strains
- Bruises
- Sprains

**Warnings:** For external use only.**When using this product**

- Avoid contact with eyes
- Do not apply to wounds or damage skin
- Do not bandage tightly

**Stop use and ask doctor if** ▪ Condition worsens ▪ Irritation occurs ▪ Symptoms persist for more than 7 days or clear up and occur again within a few days

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

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

**Directions:**

**Adults and children 2 years of age and older:**

Apply to affected area not more than 3 to 4 times daily.

**Children under 2 years of age**

Consult a doctor

**Other information** ▪ Store in a cool, dry place away from light.

**Inactive Ingredients:** Angelica Polymorpha Sinensis Root Extract, Boswellia Sacra (Frankincense) Gum/Resin Extract, Butyrospermum Parkii (Shea) Butter, Caprylic/Capric Triglyceride, Carthamus Tinctorius (Safflower) Flower Extract, Cetearyl Oliviate, Citrus Paradisi (Grapefruit) Seed Extract, Commiphora Myrrha Resin Extract, Eugenia Caryophyllus (Clove) Flower Oil, Glycerin, Glyceryl Stearate Citrate, Isopropyl Palmitate, Ligusticum Chuanxiong Root Extract, Sodium Benzoate, Sodium Hyaluronate, Stearyl Alcohol, Vitis Vinifera (Grape) Seed Oil, Xanthan Gum

**Questions or comments?**

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# SINOVEDA®

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# PROFLEXA

camphor cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83011-001
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CAMPHOR (NATURAL)</b> (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	3.3 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>SAFFLOWER</b> (UNII: 4VBL71TY4Y)	
<b>CETEARYL OLIVATE</b> (UNII: 58B69Q84JO)	
<b>CITRUS PARADISI SEED</b> (UNII: 12F08874Y7)	
<b>MYRRH</b> (UNII: JC71GJ1F3L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL STEARATE CITRATE</b> (UNII: WH8T92A065)	
<b>ISOPROPYL PALMITATE</b> (UNII: 8CRQ2TH63M)	
<b>LIGUSTICUM SINENSE SUBSP. CHUANXIONG ROOT</b> (UNII: RR83T99U97)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>GRAPE SEED OIL</b> (UNII: 930MLC8XGG)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>ANGELICA POLYMORPHA ROOT</b> (UNII: HZ12173363)	
<b>BOSWELLIA SACRA WHOLE</b> (UNII: 8O600AZLOW)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CLOVE OIL</b> (UNII: 578389D6D0)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83011-001-01	1 in 1 CARTON	09/30/2022	
1		50 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph not final	part348	09/30/2022	

**Labeler** - Sinoveda Canada Inc (242335052)

## Establishment

Name	Address	ID/FEI	Business Operations
Ec Labs Inc		205510751	manufacture(83011-001)

Revised: 9/2022

Sinoveda Canada Inc