

**RANDEX HEMP CREAM- randex hemp cream cream**  
**Randex Trading 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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**81852-001**  
**RANDEX HEMP cream**

**Active Ingredient(s)**

MSM 11% ..... Cooling Pain Relief  
Arnica montana 4.5% ..... Treat Arthritis  
Menthol 3.6% ..... Relieves muscle

**Purpose**

Active Ingredients Purpose  
MSM 11% ..... Cooling Pain Relief  
Arnica montana 4.5% ..... Treat Arthritis  
Menthol 3.6% ..... Relieves muscle

**Use**

Flammab Allergy alert: If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

**Warnings**

For external use only.

Flammab Allergy alert: If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

Stop use and ask a doctor if: Condition worsens, or if symptoms persist for more than 7 days, or clear up and reoccur.

If pregnant or breast-feeding: Ask a health professional before use.

Keep out of reach of children: If accidentally ingested, get medical help or contact a Poison Control Center immediately.

**Do not use**

- Do not use with other ointments, creams, sprays or liniments
- Do not use with heating pad or device.

When using this product:

- Avoid contact with the eyes or mucous membranes
- Do not apply to wounds or damaged skin
- Do not use with other ointments, creams, sprays or liniments
- Do not apply to irritated skin or if excessive irritation develops
- Do not bandage
- Wash hands after use with cool water
- Do not use with heating pad or device.

Stop use and ask a doctor if: Condition worsens, or if symptoms persist for more than 7 days, or clear up and reoccur.

If pregnant or breast-feeding: Ask a health professional before use.

Keep out of reach of children: If accidentally ingested, get medical help or contact a Poison Control Center immediately.

### **Directions**

Adults and children 12 years of age and older:

- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary ,but no more than 4 times daily .

Children 12 years or younger: Consult physician.

### **Other information**

Store at room temperature with the cap closed

Notice: because this product contains natural nutrients,color may vary.

### **Inactive ingredients**

Argan oil, Jojoba oil, Emu oil, Hempseed oil, Turmeric, Aloe vera, Squalane , Beeswax, Rosmarinus Officinalis leaf oil, Benzyl alcohol, Capsaicin, Carbomer940, Purified Water.

### **Package Label - Principal Display Panel**

81852-001-01 30000mg in 1 box



81852-001 Directions 1

**Drug Facts (continued)**

**If pregnant or breast-feeding:** Ask a health professional before use.  
**Keep out of reach of children:** If accidentally ingested, get medical help or contact a Poison Control Center immediately.




**When using this product:** • Avoid contact with the eyes or mucous membranes • Do not apply to wounds or damaged skin • Do not use with other ointments, creams, sprays or liniments • Do not apply to irritated skin or if excessive irritation develops • Do not bandage • Wash hands after use with cool water • Do not use with heating pad or device.

**Directions**

**Adults and children 12 years of age and older:** • apply generously to affected area • massage into painful area until thoroughly absorbed into skin • repeat as necessary ,but no more than 4 times daily .  
**Children 12 years or younger:** Consult physician.

# RANDEX

## HEMP CREAM FOR PAIN RELIEF

## **Drug Facts (continued)**

### **Other Information**

Store at room temperature with the cap closed  
Notice: because this product contains natural nutrients,color may vary.

### **Inactive Ingredients**

Argan oil, Jojoba oil, Emu oil, Hemp seed oil, Turmeric, Aloe vera, Squalane , Beeswax, Rosmarinus Officinalis leaf oil, Benzyl alcohol, Capsaicin, Carbomer940, Purified Water.

## **Drug Facts**

### **Active Ingredients**

	<b>Purpose</b>
MSM 11% .....	Cooling Pain Relief
Arnica montana 4.5% .....	Treat Arthritis
Menthol 3.6% .....	Relieves muscle

**Uses** temporarily relieves minor pain associated with:

- arthritis • backache • strains • sprains

### **Warnings**

For external use only.

**Flammab Allergy alert: If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.**

**Stop use and ask a doctor if:** Condition worsens, or if symptoms persist for more than 7 days, or clear up and reoccur.

81852-001 label



## RANDEX HEMP CREAM

randex hemp cream cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81852-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ) (ARNICA MONTANA FLOWER - UNII:OZ0E5Y15PZ)	ARNICA MONTANA FLOWER	4.5 mg in 100 mg
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT) (DIMETHYL SULFONE - UNII:9H4PO4Z4FT)	DIMETHYL SULFONE	11 mg in 100 mg

<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL	5.6 mg in 100 mg
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### Inactive Ingredients

Ingredient Name	Strength
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>CAPSAICIN</b> (UNII: S07O44R1ZM)	
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>TURMERIC</b> (UNII: 856YO1Z64F)	
<b>ARGAN OIL</b> (UNII: 4V59G5UW9X)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>EMU OIL</b> (UNII: 344821WD61)	
<b>CANNABIS SATIVA SEED OIL</b> (UNII: 69VJ1LPN1S)	
<b>ROSEMARY OIL</b> (UNII: 8LGU7VM393)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81852-001-01	30000 mg in 1 BOX; Type 0: Not a Combination Product	03/30/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/30/2020	

**Labeler** - Randex Trading Inc. (117947972)

### Establishment

Name	Address	ID/FEI	Business Operations
Randex Trading Inc.		117947972	manufacture(81852-001)

Revised: 4/2021

Randex Trading Inc.