

**EXTRA STRENGTH PAIN RELIEVER- capsaicin and menthol, unspecified form cream**  
**HPI Health Products 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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**Extra Strength Pain Reliever**

***Drug Facts***

<b><i>Active Ingredient</i></b>	<b><i>Purpose</i></b>
Capsaicin 0.035%	Topical analgesic
Menthol 3%	Topical analgesic

**Uses**

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

- simple backache
- arthritis
- bruises
- strains
- sprains

**Warnings**

- **For external use only.**

**When using this product**

- use only as directed
- do not bandage
- do not use with a heating pad
- avoid contact with eyes and mucous membranes
- do not apply to wounds or damaged, broken or irritated skin
- a transient burning sensation may occur upon application but generally disappears in several days.
- if severe burning sensation occurs, discontinue use
- do not expose the area treated with product to heat or direct sunlight
- do not use if you are allergic to capsaicin or chili peppers

**Stop use and ask a doctor if**

- condition worsens
- redness is present
- irritation develops
- 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 care 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 over 18 years:**

- apply to affected area
- massage into painful area until thoroughly absorbed
- repeat if necessary, but no more than 3 to 4 times daily
- **WASH HANDS WITH SOAP AND WATER AFTER APPLYING**
- **children 18 years and younger:** ask a doctor

**Other information**

- store at 20-25° C (68-77° F)

**Inactive ingredients**

carbomer, ethyl alcohol, germaben II, triethanolamine, water

**Questions or comments?**

Call us toll free at (877) 514-3132 between 9am and 4pm (PST), Monday through Friday. Visit us on the web at [lakotaherbs.com](http://lakotaherbs.com)

Manufactured exclusively for  
and distributed by:  
Natural Pain Relief Agency Inc.  
Phoenix, AZ 85086

**PRINCIPAL DISPLAY PANEL - 57 mL Bottle Box****LaKOTA®**

SOFT-TOUCH PAIN RELIEVER

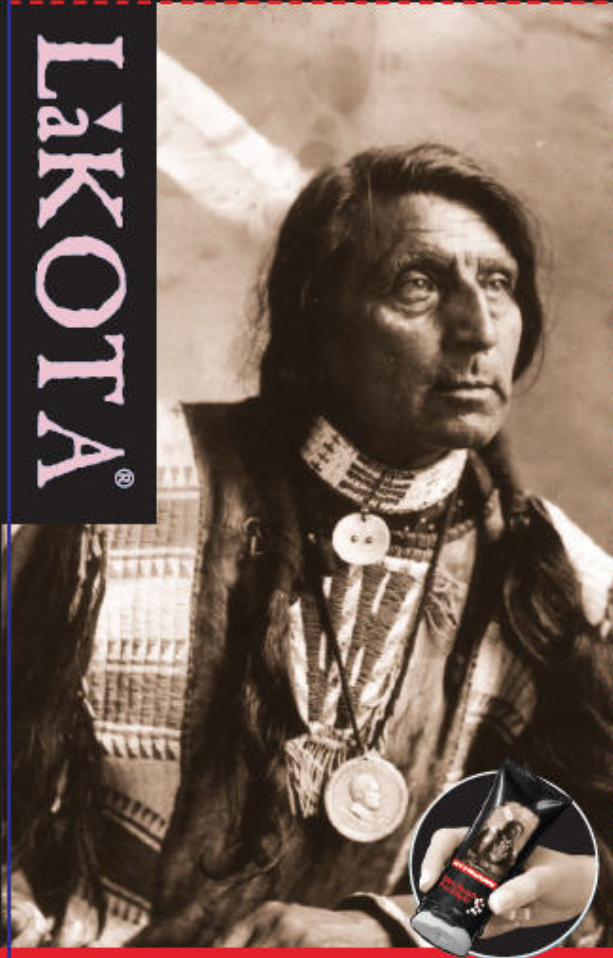
**Extra Strength  
Pain Reliever**

Capsaicin and Menthol -  
Topical analgesic

**57mL (2 fl oz)**

# LAKOTA®

LAKOTA®



Natural Source Pain Relief

“Get  
medicine  
that  
works!”

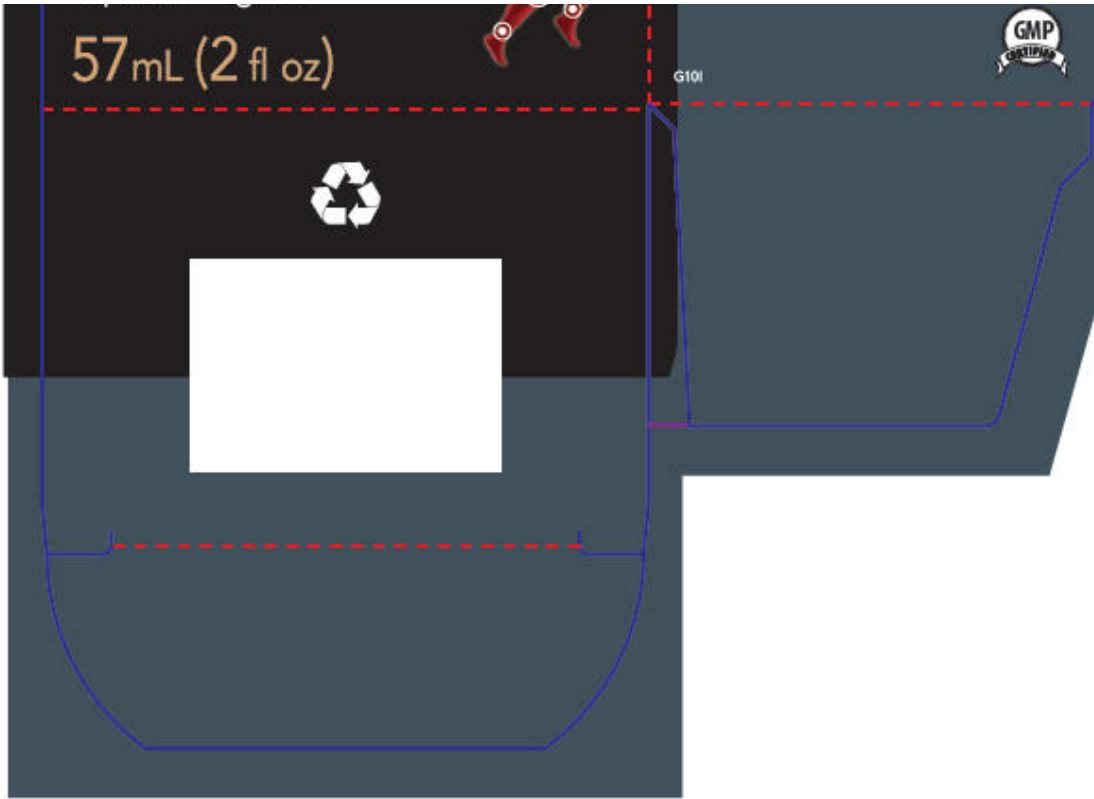
SOFT-TOUCH PAIN RELIEVER

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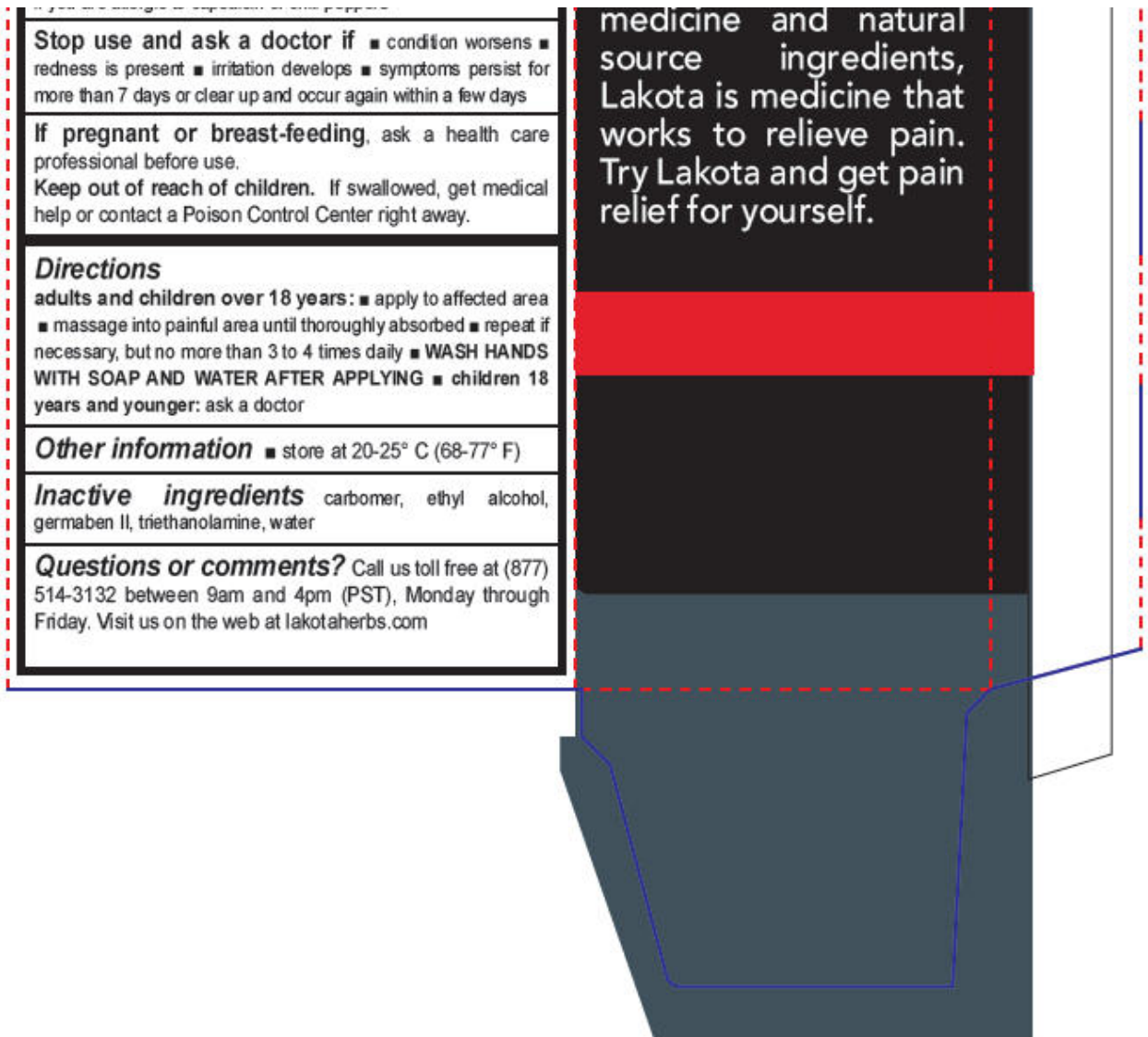
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## Natural Source Pain Relief

Natural source pain relief that works. Works on joint pain, muscle pain, and backache. A powerful pain reliever made from a rare pepper extract and natural source menthol. It works fast.

Rooted in traditional



## EXTRA STRENGTH PAIN RELIEVER

capsaicin and menthol, unspecified form cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59092-002
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
capsaicin (UNII: S07O44R1ZM) (capsaicin - UNII:S07O44R1ZM)	capsaicin	0.35 mg in 1 mL
menthol, unspecified form (UNII: L7T10EIP3A) (menthol, unspecified form - UNII:L7T10EIP3A)	menthol, unspecified form	30 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
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<b>carbomer interpolymers type A (allyl sucrose crosslinked)</b> (UNII: 59TL3WG5CO)	
<b>alcohol</b> (UNII: 3K9958V90M)	
<b>diazolidinyl urea</b> (UNII: H5RIZ3MPW4)	
<b>trolamine</b> (UNII: 9O3K93S3TK)	
<b>water</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	BROWN	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59092-002-01	1 in 1 BOX		
1		57 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	12/01/2014	

**Labeler** - HPI Health Products Inc. (202932864)

Revised: 10/2014

HPI Health Products Inc.