

**INSTAFLEX PAIN RELIEF CREAM- menthol cream**  
**Healthy Directions, LLC**

*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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**Instaflex Pain Relief Cream**

*Drug Facts*

**Active Ingredient**

Menthol (1.25%)

**Purpose**

Topical Analgesic

**Uses** Temporarily relieves minor aches and pains

of muscles and joints associated with

- simple backache
- arthritis
- strains
- sprains
- bruises

**Warnings**

**For external use only**

**Do not use**

- with a heating pad, may blister skin
- on open wounds or damaged skin

**Ask a doctor before use if you have**

redness over the affected area

**When using this product**

- Use only as directed
- avoid contact with eyes
- do not bandage tightly

**Stop use and ask a doctor if**

- skin redness or excessive skin irritation develops
- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again in a few days

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions Adult and children 12 years of**

**age and older:** Apply to affected area no more than 3-4 times daily. **Children under 12 years**

**of age:** Consult a doctor.

***Other information***

□Keep product at room temperature and humidity [59-86°F (15-30°C), 40% RH]. Do not freeze. For Lot Number and Expiration Date, see crimp at end of tube.

***Inactive ingredients*** C13-14 Isoparaffin, Citrus Aurantium Dulcis (Orange) Oil, Ethylhexylglycerin, Eucalyptus Globulus Oil, Glyceryl Stearate, Laureth-7, Oxygenated Corn Oil, PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Polysorbate-20, Water

**PAIN RELIEVING CREAM**

**Instaflex**

**PAIN RELIEF**

Formulated with an

**EXCLUSIVE OXYGENATED OIL**

**FAST RELIEF FOR ARTHRITIS,**

**JOINT & MUSCLE PAIN**

**POWERFUL PAIN RELIEF STARTS IN MINUTES,**

**LASTS FOR HOURS**

**Deep Penetrating | Fast Acting | Pleasant Smelling | Non-Greasy**

**CLINICALLY STUDIED | DOCTOR DEVELOPED**

Net wt. [2/4] oz ([57/113] g)

CLINICALLY STUDIED · DOCTOR DEVELOPED

PAIN RELIEVING CREAM

# Instaflex<sup>®</sup> PAIN RELIEF



Formulated with an EXCLUSIVE OXYGENATED OIL

- ✓ Deep Penetrating
- ✓ Fast Acting
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Net wt. 2 oz (57 g)

### Drug Facts

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SKU: IPC 02 M12000, R-119



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Distributed by

**HEALTHY DIRECTIONS**

Bethesda, MD 20817

healthydirections.com

Customer Service: 1-888-348-8811



CLINICALLY STUDIED · DOCTOR DEVELOPED

PAIN RELIEVING CREAM

**Instaflex**<sup>®</sup>  
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Formulated with an  
EXCLUSIVE OXYGENATED OIL



✓ Deep Penetrating ✓ Fast Acting ✓ Pleasant Smelling ✓ Non-Greasy

Net wt. 4 oz (113 g)

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SKU: IPC 02 M14000, R-119



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Doctor  
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Net wt. 4 oz (113 g)



**Clinical Study Shows  
Nearly TWICE the Relief!**  
Instaflex<sup>®</sup> Oxygenated Pain Relief Cream  
vs. Menthol-Only Pain Cream

A randomized, double-blind, placebo-controlled study found that Instaflex Pain Relief Cream was nearly twice as effective at relieving pain as a comparable menthol-only rub. Instaflex reported improvements in pain, mobility and flexibility.

**HEALTHY REACTIONS**

Developed by  
Lumina Therapeutics, Inc., PO Box 100  
Pharmaceuticals, Inc.

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

**Stop use and ask a doctor if you notice:**  
Swelling or redness of the skin  
Worsening of your condition or development of a new condition  
Nausea or vomiting  
Dizziness or lightheadedness  
If you are pregnant, stop use and contact your doctor.

**When using this product:** Use only as directed on the attached label.

**Use before use if you have:**  
Allergies to any of the ingredients listed on the label  
Open wounds or damaged skin

**Do not use with a heating pad, hot water bottle, or other heat source.**

**For external use only.**

**Warnings:**  
Do not use if you are allergic to any of the ingredients listed on the label.  
Do not use if you are pregnant, nursing, or trying to become pregnant.  
Do not use if you are taking any other medications.

**Other information:** Keep product at room temperature and tightly sealed (59°F - 86°F / 15°C - 30°C).  
Keep away from heat, fire, and flame.  
Keep out of reach of children.

**Drug Facts (continued)**  
Contains Menthol, Eucalyptus, Camphor, and other natural oils.  
For more information, visit our website at [www.instaflex.com](http://www.instaflex.com).

**RELIEF IN MINUTES, LASTS FOR HOURS**

## INSTAFLEX PAIN RELIEF CREAM

menthol cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:700 15-665
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	12.5 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
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<b>C13-14 ISOPARAFFIN</b> (UNII: E4F12ROE70)
<b>ORANGE OIL</b> (UNII: AKN3KSD11B)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>LAURETH-7</b> (UNII: Z95S6G8201)
<b>CORN OIL</b> (UNII: 8470G57WFM)
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>POLYACRYLAMIDE (CROSSLINKED; 0.01-0.2 MOLE PERCENT BISACRYLAMIDE)</b> (UNII: RHA9LWJ494)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>WATER</b> (UNII: 059QF0K00R)

### Product Characteristics

<b>Color</b>	white	<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:70015-665-02	1 in 1 CARTON	01/01/2019	
1		57 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:70015-665-04	1 in 1 CARTON	01/01/2019	
2		113 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:70015-665-01	1 in 1 CARTON	06/10/2020	
3		28 g in 1 TUBE; 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	01/01/2019	

**Labeler** - Healthy Directions, LLC (150261183)

### Establishment

Name	Address	ID/FEI	Business Operations
Pure Source, LLC		080354456	manufacture(70015-665)