

**INSTAFLEX EXTRA STRENGTH PAIN RELIEF CREAM- menthol, methyl salicylate 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 Extra Strength Pain Relief Cream**

*Drug Facts*

**Active Ingredients**

Menthol (2.5%)

Methyl Salicylate (10%)

**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 Adults 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

## **EXTRA STRENGTH PAIN RELIEVING CREAM**

**Instaflex**

### **PAIN RELIEF**

Formulated with an

EXCLUSIVE OXYGENATED OIL

**FAST, EXTRA STRENGTH RELIEF FOR**

**ARTHRITIS, JOINT & MUSCLE PAIN**

**DOUBLE THE PAIN-FIGHTING INGREDIENTS**

**DOUBLE THE MENTHOL POWER\***

**Deep Penetrating | Fast Acting | Great for Nighttime Use**

**EXTRA STRENGTH | DOCTOR DEVELOPED**

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

# RELIEF IN MINUTES, LASTS FOR HOURS



Double the Menthol and Pain-Fighting Ingredients\*



Instaflex Extra Strength rubs out your toughest aches and pains:

- ✔ Arthritis
- ✔ Strains & Sprains
- ✔ Backache
- ✔ Workouts
- ✔ Sports
- ✔ Nighttime Pain
- ✔ Everyday Activities

<p><b>Drug Facts</b></p> <p><b>Active Ingredients</b>                  Menthol 2.5%                  100% Menthyl Salicylate                  100% Peppermint Oil</p> <p>These ingredients temporarily numb and soothe the skin, and help relieve pain. Menthyl salicylate is a topical form of aspirin. Menthyl salicylate is absorbed through the skin and acts like aspirin to help relieve pain.</p> <p><b>Warnings</b>                  For external use only.                  Do not use with a heating pad, may blister skin.                  Do not use on open wounds or damaged skin.                  Ask a doctor before use if you have redness, swelling, or a rash on the affected area.</p> <p><b>When using this product</b> Use only as directed. Do not use if you have an allergy to aspirin, salicylates, or menthol. Do not use if you are taking blood thinners. Do not use if you are taking other pain relievers. Do not use if you are taking other topical products. Do not use if you are taking other topical products. Do not use if you are taking other topical products.</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b> Adults and children 13 years of age and older: Apply to affected area no more than 3-4 times daily. Children under 12 years of age: Consult the doctor.</p> <p><b>Other information</b> Keep product out of reach of children. Store in a cool, dry place. Do not use if you are taking other topical products. Do not use if you are taking other topical products. Do not use if you are taking other topical products.</p> <p><b>Contains</b> Menthyl Salicylate, Menthol, Peppermint Oil, Eucalyptus Globulus Oil, Glycol Stearate, Carbomer 7, Organosol (Dimethyl Siloxane), Hydroxyethyl Methacrylate, Poly-100 Silicone, Hydroxyethyl Methacrylate, Poly-100 Silicone, Water.</p> <p>*Compare it to Regular Instaflex Pain Relief Creams. Distributed by HEALTHY DIRECTIONS Bethesda, MD 20817 healthydirections.com Customer Service: 1-888-348-8811</p>
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Lot No. / Exp. Date:

SKU: IES 02 M12000, R-118



- ✔ Deep Penetrating
  - ✔ Fast Acting
  - ✔ Great for Nighttime Use
- Net Wt. 2 oz (57 g)

Extra Strength Doctor Developed



EXTRA STRENGTH PAIN RELIEVING CREAM

DOUBLE THE PAIN-FIGHTING INGREDIENTS  
 DOUBLE THE MENTHOL POWER\*



FAST, EXTRA STRENGTH RELIEF FOR ARTHRITIS, JOINT & MUSCLE PAIN

EXTRA STRENGTH - DOCTOR DEVELOPED

EXTRA STRENGTH • DOCTOR DEVELOPED

EXTRA STRENGTH PAIN RELIEVING CREAM

# Instaflex<sup>®</sup>

PAIN RELIEF



Formulated with an  
EXCLUSIVE OXYGENATED OIL

Deep Penetrating ✓ Fast Acting ✓ Great for Nighttime Use

Net wt. 2 oz (57 g)

### Drug Facts

#### Active Ingredients

Menthol (2.5%)	.....	Topical Analgesic
Methyl Salicylate (10%)	.....	Topical Analgesic

#### Purpose

**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** Adults 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.

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**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

SKU: IES 02 M12000, R-118

Distributed by



**HEALTHY DIRECTIONS**

Bethesda, MD 20817  
healthydirections.com

Customer Service: 1-888-348-8811



**EXTRA STRENGTH** ■ DOCTOR DEVELOPED

**EXTRA STRENGTH PAIN RELIEVING CREAM**

**Instaflex<sup>®</sup>**  
PAIN RELIEF

Formulated with an  
**EXCLUSIVE OXYGENATED OIL**



✓ Deep Penetrating ✓ Fast Acting ✓ Great for Nighttime Use

Net wt. 4 oz (113 g)

**Drug Facts**

<b>Active Ingredients</b>	<b>Purpose</b>
Menthol (2.5%) .....	Topical Analgesic
Methyl Salicylate (10%) .....	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

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**Directions** Adults 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

SKU: IES 02 M14000, R-118

Distributed by



**HEALTHY DIRECTIONS**

Bethesda, MD 20817  
healthydirections.com  
Customer Service: 1-888-348-8811

**INSTAFLEX EXTRA STRENGTH PAIN RELIEF CREAM**

menthol, methyl salicylate cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:700 15-660
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
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MENTHOL (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)	MENTHOL	25 mg in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	100 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
ORANGE OIL (UNII: AKN3KSD11B)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LAURETH-7 (UNII: Z95S6G8201)	
CORN OIL (UNII: 8470G57WFM)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYACRYLAMIDE (CROSSLINKED; 0.01-0.2 MOLE PERCENT BISACRYLAMIDE) (UNII: RHA9LWJ494)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	

### Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70015-660-02	1 in 1 CARTON	03/01/2019	
1		57 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:70015-660-04	1 in 1 CARTON	03/01/2019	
2		113 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	03/01/2019	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Pure Source, LLC		080354456	manufacture(70015-660)