

INSTAFLEX PAIN RELIEF CREAM- menthol cream
Adaptive Health, 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.

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 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

PAIN RELIEVING CREAM

Instaflex

PAIN RELIEF

Formulated with an

EXCLUSIVE OXYGENATED OIL

FAST RELIEF FOR ARTHRITIS,

JOINT & MUSCLE PAIN

Proud Partner of the

Arthritis

Foundation

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[®]

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

Net wt. 2 oz (57 g)

Drug Facts

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Menthol (1.25%)	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.

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Distributed by

 **ADAPTIVE**
HEALTH

Charlotte, NC 28202
adaptivehealth.com
Customer Service: 1-866-599-9491

SKU: IPC 02 M12000, R-118



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PAIN RELIEVING CREAM

Instaflex[®]

PAIN RELIEF

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EXCLUSIVE OXYGENATED OIL



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

Net wt. 4 oz (113 g)

Drug Facts

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Menthol (1.25%)	Topical Analgesic

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Warnings

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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.

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Formulated with an
**EXCLUSIVE
OXYGENATED OIL**

**FAST RELIEF FOR ARTHRITIS,
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PAIN RELIEVING CREAM

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PAIN RELIEF

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- ✔ Fast Acting
- ✔ Pleasant Smelling
- ✔ Non-Greasy

**Clinically
Studied
Doctor
Developed**

Net wt. 4 oz (113 g)



Lot No. / Exp. Date:

SKU: POC 02 M14000,
R-11B



**Clinical Study Shows
Nearly Twice the Relief!**
Instaflex[®] Oxygenated Pain Relief Cream
vs. Menthol-Only Pain Cream

A randomized,
double-blind,
placebo-controlled
study found that
Instaflex Pain Relief
Cream was nearly
2x as effective
at relieving pain
as a comparable
menthol-only rub.
Adult subjects using
Instaflex reported
improvements in
pain, mobility, and
flexibility.

ADAPTIVE
Proud Partner of the
Arthritis Foundation

ADAPTIVE
Proud Partner of the
Arthritis Foundation

Drug Facts (continued)

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

Directions
Apply to the affected area. Rub gently. Do not use on open wounds or damaged skin. Do not use with a heating pad, ray burner, skin lamp, or other heat source. Do not use on the face.

Other information
Keep this product at room temperature and humidity (59-86°F / 15-30°C). Do not freeze. For Lot Number and Expiration Date, see bottom of carton.

Contains
Menthol, Eucalyptus, Camphor, Thymol, and other natural oils.

RELIEF IN MINUTES, LASTS FOR HOURS

INSTAFLEX PAIN RELIEF CREAM

menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72779-100
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
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: 059QF0K00R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72779-100-02	1 in 1 CARTON	01/01/2019	
1		57 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:72779-100-04	1 in 1 CARTON	01/01/2019	
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	01/01/2019	

Labeler - Adaptive Health, LLC (832215177)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source, LLC		080354456	manufacture(72779-100)