

**OXYRUB PRO PAIN RELIEF CREAM, 4OZ- 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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**OxyRub PRO Pain Relief Cream, 4oz**

**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 backaches
- arthritis
- strains
- sprains
- bruises

***Warnings***

**For external use only:** Use only as directed

**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**

- avoid contact with eyes
- do not bandage tightly

**Stop use and consult 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***

Store at room temperature. For Lot Number and Expiration Date, see bottom of the carton or crimp at end of tube.

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

Dr. Pergolizzi

**OxyRub**

**PRO**

**Pain Relief Cream**

**PROFESSIONAL STRENGTH**

MUSCLE & JOINT

PAIN RELIEF

RAPIDLY

ABSORBED

DEEP

PENETRATING

Net Wt. 4 oz (114 g)

Distributed by

**HEALTHY DIRECTIONS**

6710A Rockledge Drive, Suite 500

Bethesda, MD 20817

PROFESSIONAL STRENGTH

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**Drug Facts**

| Active Ingredient       | Purpose           |
|-------------------------|-------------------|
| Menthol (2.5%)          | Topical Analgesic |
| Methyl Salicylate (10%) | Topical Analgesic |

**Uses** temporarily relieves minor aches and pains of muscles and joints associated with  
 ■ simple backaches ■ arthritis ■ strains  
 ■ sprains ■ bruises

**Warnings**

**For external use only** ■ Use only as directed  
**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** ■ avoid contact with eyes ■ do not bandage tightly

**Stop use and consult 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

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**Inactive ingredients**

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

Distributed by  
**HEALTHY DIRECTIONS**  
 6710A Rockledge Drive, Suite 500  
 Bethesda, MD 20817

“OxyRub PRO represents an important alternative to other treatments for managing pain.”



- Professional Strength Relief
- Fast Acting
- Pleasant Scent
- No Greasy Residue
- Rubs on Smoothly
- Absorbs Quickly

MUSCLE & JOINT PAIN RELIEF  
 RAPIDLY ABSORBED  
 DEEP PENETRATING

**OxyRub PRO** Pain Relief Cream

Dr. Pergolizzi

Doctor-developed OxyRub® PRO offers fast, temporary, extra strength relief of everyday pain from arthritis, muscle aches, strains, joint pain, and more.

**Perfect for:**

- ☑ Knees
- ☑ Shoulders
- ☑ Neck
- ☑ Back
- ☑ Hands and Wrists
- ☑ Knuckles
- ☑ Hips, Ankles, Toes

Net Wt. 4 oz (114 g)

**OXYRUB PRO PAIN RELIEF CREAM, 4OZ**

menthol, methyl salicylate cream

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:70015-655 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)                  | MENTHOL           | 25.0 mg in 1 g  |
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) | METHYL SALICYLATE | 100.0 mg in 1 g |

**Inactive Ingredients**

| Ingredient Name                       | Strength |
|---------------------------------------|----------|
| 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)   |  |
| C13-14 ISOPARAFFIN (UNII: E4F12ROE70)  |  |

### Product Characteristics

|          |       |              |  |
|----------|-------|--------------|--|
| Color    | white | Score        |  |
| Shape    |       | Size         |  |
| Flavor   |       | Imprint Code |  |
| Contains |       |              |  |

### Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70015-655-04 | 1 in 1 CARTON                                      | 09/01/2017           |                    |
| 1 |                  | 114 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                                  | 09/01/2017           |                    |

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

### Establishment

| Name             | Address | ID/FEI    | Business Operations    |
|------------------|---------|-----------|------------------------|
| Pure Source, LLC |         | 080354456 | manufacture(70015-655) |