DR. TEALS PRE AND POST WORKOUT PAIN RELIEF- menthol cream PDC Brands

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.

Dr. Teal's Pre and Post Workout Pain Relief Cream

Drug Facts

Active ingredients

Menthol 10%

Purpose

Topical Analgesic

Uses

Temporarily relieves the minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

IFor external use only

Do not use

- on wounds or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like conditions

Ask a doctor before use if you have

• redness over the affected area

When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if

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

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Directions

- Use only as directed
- | Adults and children 12 years of age and older:

Apply a thin layer to affected area not more than 3 to 4 times daily, allowing minimum of 2-3 hours in between applications.

• **©Children under 12 years of age:** Dask a doctor

Other information

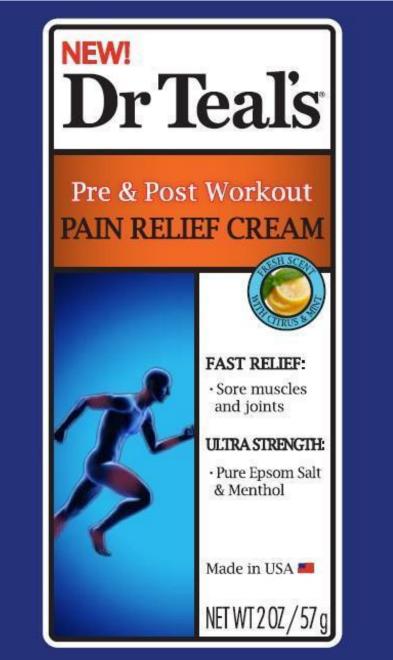
• Store between 20° and 25°C (68° and 77°F)

Inactive ingredients:

Cetearath 20, Cetyl Alcohol, Cetyl Ester, Ethylhexylglycerin, Fragrance(Parfum), Glycerin, Glyceryl Stearate SE, Isopropyl Palmitate, Magnesium Sulfate (Epsom Salt), Phenoxyethanol, Polyquaternium 37, PPG-1 Trideceth-6, Propylene Glycol Dicaprylate/Dicaprate, Simethicone, Stearic Acid, Stearyl Alcohol, Triethanolamine, Water (Aqua).

Principal Display Panel Dr. Teal's Pre & Post Workout Pain Relief Cream 2 oz./57g

NDC: 61012-010-57



Label1.jpg Label2.jpg

Drug Facts Active ingredients Purpose Menthol 10%. Topical Analgesic Uses temporarily relieves the minor aches and pains of muscles and joints associated with: simple backache arthritis strains bruises sprains Warnings For external use only Do not use ■ on wounds or damaged skin ■ with a heating pad ■ on a child under 12 years of age with arthritis-likeconditions Ask a doctor before use if you have redness over the affected area When using this product avoid contact with eyes or mucous membranes do not bandage tightly Stop use and ask a doctor if condition worsens or symptoms persist for more than 7 days symptoms clear up and occur again within a few days excessive skin irritation occurs If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children, If swallowed, get medical help or contact a Poison Control Center immediately. Directions Use only as directed

Drug Facts (continued)

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Dr Teal's® Pain Relief Cream is not tested on animals.

Distributed by:

□PARFUMS de COEUR*

Darien, CT 06820 QUESTIONS CALL (800) 887-2738

Made in USA

www.drteals.com

DR. TEALS PRE AND POST WORKOUT PAIN RELIEF

menthol cream

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:61012-010 Route of Administration TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
CETYL ESTERS WAX (UNII: D072FFP9GU)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)		
ISOPROPYL PALMITATE (UNII: 8 CRQ2TH6 3M)		
MAGNESIUM SULFATE (UNII: DE08037SAB)		
PHENO XYETHANO L (UNII: HIE492ZZ3T)		
POLYQUATERNIUM 37 (200 MPA.S) (UNII: 67C1D6YV24)		

PPG-1 TRIDECETH-6 (UNII: 1K7417JX6Q)	
PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61012-010-01	1 in 1 CARTON		
1	NDC:61012-010-57	57 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	02/10/2015		

Labeler - PDC Brands (037512746)

Establishment				
Name	Address	ID/FEI	Business Operations	
Dhaliwal Laboratories, LLC		016754201	manufacture (6 10 12-0 10)	

Revised: 12/2015 PDC Brands