# TEDS TOPICAL PAIN CREAM- methyl salicylate 10% cream Cosmetic Specialty Labs, Inc.

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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### ted's Brain Science Products pain cream

#### **Active ingredient**

Methyl Salicylate - 10%

#### **Purpose**

Topical Pain Relief

#### Uses

For the temporarily relief of minor aches and pains of muscles and joints associated with: • simple back ache • arthritis • strains • bruises and • sprains

#### **Warnings**

#### For external use only [

#### **Allergy Alert**

If you had prior allergic reaction to aspirin or salicylate, please consult a physician before use.

#### Do not use

- on wounds or damaged skin
- with a heating pad

#### Ask a physician before use if

• you have redness over the affected area

#### When using this product

□ • use only as directed • avoid contact with eyes and muscous membranes • do not bandage tightly

#### Stop use and ask a physician 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 • pregnant or breast-feeding

#### Keep out of reach of the children

In case of accidental ingestion, get medical help or contact a Poison Control Center right away

#### Directions

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#### adults and children 2 years of age and older:

• apply to affected area not more than 3 or 4 times daily

## children under 2 years of age: consult a physician

#### Other Information

Store at 20°C to 25°C (68°F - 77°F)

## **Inactive ingredients:**

Aqua (deionized water), Arnica Montana (arnica) Extract, boswellia serrata extract, cetearyl olivate, cetyl alcohol, dimethyl sulfone (MSM), ethylhexylglycerin, glycerin, glyceryl stearate, PEG-100 stearate, phenoxyethanol, polysorbate 20, resveratrol, sodium laurylglucosides, hydroxypropylsulfonate, sorbitan olivate, stearic acid

## **Package Labeling**



Printing

pain cream

topical analgesic with resveratrol

net wt 3 oz (85 g)

## Drug Facts

Active Ingredients: Methyl Salicylate 10.0%

#### Uses:

For the temporary relief of minor muscles and joints associated w arthritis + strains + bruises are

## Warnings:

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hydroxypropyleulforrata, sorbitari

#### **TEDS TOPICAL PAIN CREAM**

methyl salicylate 10% cream

#### **Product Information**

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:58133-210

Route of Administration TOPICAL

**Active Ingredient/Active Moiety** 

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
<b>DIMETHYL SULFONE</b> (UNII: 9 H4PO 4Z4FT)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0KO0R)	
RESVERATROL (UNII: Q369O8926L)	
SODIUM LAURYL GLYCOL CARBOXYLATE (UNII: 8L0472VMYL)	
SODIUM HYDROXYPROPYLSULFONATE LAURYLGLUCOSIDE-7 CROSSPOLYMER (UNII: K9R4VJQ1IB)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
BOSWELLIA SERRATA RESIN OIL (UNII: 5T1XCE6K8K)	

l	Packaging			
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1 NDC:58133-210-03	85 g in 1 TUBE; Type 0: Not a Combination Product	0 3/2 1/20 19	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	03/21/2019			

# Labeler - Cosmetic Specialty Labs, Inc. (032973000)

## Registrant - Cosmetic Specialty Labs, Inc. (032973000)

Establishment					
Name	Address	ID/FEI	Business Operations		
Cosmetic Specialty Labs, Inc.		032973000	manufacture(58133-210)		

Revised: 1/2021 Cosmetic Specialty Labs, Inc.