# TRAUMA LESS- menthol ointment Natures Formulae Health Products Ltd.

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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# **Trauma Less Topical Analgesic Ointment**

# IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USING. KEEP THIS PACKAGE FOR FULL INFORMATION.

#### **DRUG FACTS**

# Active ingredient

Menthol 1.27%

## **Purpose** Topical Analgesic

*Uses* For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains

# **Warnings**

## For external use only.

#### Do not use

- on wounds or damaged skin
- if allergic to plants of the asteraceae/compositae/daisy family.

## When using this product

- avoid contact with the eyes
- do not bandage tightly

#### Stop use and ask a doctor if

condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

# If pregnant or breast-feeding,

ask a doctor before use.

## Keep out of reach of children.

If product is 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

not more than 3 times daily.

• Not recommended for children under 12 years of age.

# **Inactive ingredients**

Arnica montana flower extract, beeswax (yellow), olive oil, and peppermint oil.

#### **Questions?**

1-877-275-7253

©Distributed by: SAJE NATURAL WELLNESS 500-88 E. Pender St. Vancouver, BC Canada V6A 3X3 | saje.com | **1-877-275-7253** | Made by our friends in Canada

## DO NOT USE IF SECURITY SEAL AROUND TIN IS BROKEN OR MISSING.

SKU 435301

Lift Here

We support recycling. Please recycle where possible.

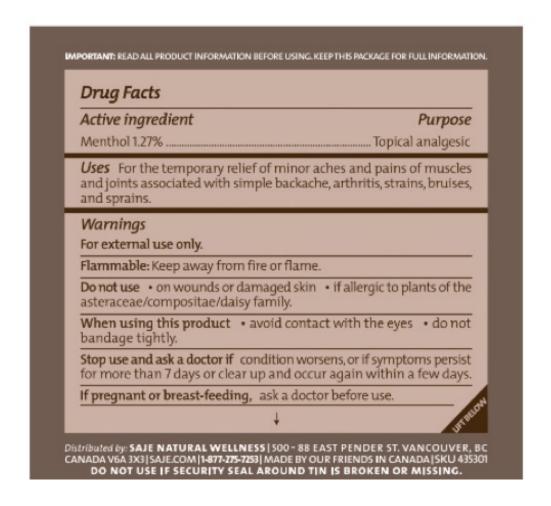
# **Trauma Less Topical Analgesic Ointment**

Saje® Natural Wellness

#### Trauma Less

## **Topical Analgesic Ointment**

net wt. 1.91 oz | 54.1 g and net wt. 0.47 oz | 13.5 g



## lift here

# Drug Facts (continued)

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WE SUPPORT RECYCLING. PLEASE RECYCLE WHERE POSSIBLE.





# TRAUMA LESS

menthol ointment

# **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69204-010

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength
I	MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	12.7 mg in 1 g

# **Inactive Ingredients**

Ingredient Name	Strength
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

# **Product Characteristics**

Color	ye llo w	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

1	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:69204-010-01	1 in 1 BOX	10/16/2016		
1		$54.1\mathrm{g}$ in $1\mathrm{CANISTER}$ ; Type $0:\mathrm{Not}\mathrm{a}$ Combination Product			
2	2 NDC:69204-010-02 13.5 g in 1 CANISTER; Type 0: Not a Combination Product		10/16/2016		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	10/16/2016			

# **Labeler** - Natures Formulae Health Products Ltd. (241385587)

Establishment				
Name	Address	ID/FEI	Business Operations	
Natures Formulae Health Products Ltd.		241385587	manufacture(69204-010)	

Revised: 10/2018 Natures Formulae Health Products Ltd.