

## **STRESSA BACK AND NECK PAIN RELIEVING- menthol oil**

### **Stressa Incorporated**

*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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### **Stressa™ Back & Neck Pain Relieving Oil**

#### ***Drug Facts***

#### **Active ingredient**

Menthol 1.25%

#### **Purpose**

topical analgesic

#### **Uses**

For the temporary relief of pain associated with

- simple backache
- strains
- bruises
- sprains

#### **Warnings**

**For external use only.**

#### **When using this product**

- avoid contact with eyes
- do not bandage tightly,

#### **Stop use and ask a doctor if**

- conditions worsen or symptoms persist for more than 7 days
- symptoms clear up and occur again within 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 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.

Children under 2 years of age: Consult a doctor.

#### **Inactive ingredients**

almond oil, alpha tocopherol (vitamin E), apricot kernel oil, arabica coffee oil, basil oil, cananga oil, european hazelnut oil, galbanum oil, hyssop oil, lemon juice, methyl salicylate, nutmeg oil, picea mariana leaf oil, pine needle oil (pinus sylvestris), rosemary oil, sage oil, wheat germ

**PRINCIPAL DISPLAY PANEL - 240 mL Bottle Label**

**Stressa™**

**back & neck  
pain relieving oil**

*all natural formula  
for the soothing relief  
of tense and sore  
muscles*

NET WT  
8 fl oz (240 mL)



**back & neck  
pain relieving cream**

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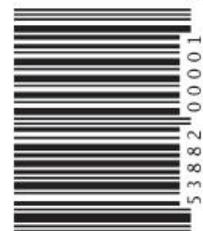
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NDC 53882-002-03

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LOT /  
EXP



menthol oil

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53882-002
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Menthol</b> (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	1 g in 93 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ALMOND OIL (UNII: 66YXD4DKO9)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
BASIL OIL (UNII: Z129UMU8LE)	
ARABICA COFFEE OIL (UNII: IK55HKE887)	
GALBANUM OIL (UNII: 211UF7M8N1)	
EUROPEAN HAZELNUT OIL (UNII: 8RQ2839AVG)	
HYSSOP OIL (UNII: 173D71924B)	
LEMON OIL (UNII: I9GRO824LL)	
NUTMEG OIL (UNII: Z1CLM48948)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
SAGE OIL (UNII: U27K0H1H2O)	
PINE NEEDLE OIL (PINUS SYLVESTRIS) (UNII: 5EXL5H740Y)	
PICEA MARIANA LEAF OIL (UNII: Q1J49L1A5O)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
WHEAT GERM (UNII: YR3G369F5A)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
CANANGA OIL (UNII: 8YOY78GNNX)	

### Product Characteristics

<b>Color</b>	ORANGE (Clear)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:53882-002-01	60 mL in 1 BOTTLE, PLASTIC		
2	NDC:53882-002-02	118 mL in 1 BOTTLE, PLASTIC		
3	NDC:53882-002-03	240 mL in 1 BOTTLE, PLASTIC		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	08/01/2014	

**Labeler** - Stressa Incorporated (031377428)

## Establishment

Name	Address	ID/FEI	Business Operations
Stressa Incorporated		031377428	MANUFACTURE(53882-002)

Revised: 8/2014

Stressa Incorporated