

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

### **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 Cream**

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

#### **Active ingredient**

Menthol 1.25%

#### **Purpose**

topical analgesic

#### **Uses**

For the temporary relief of minor aches & pains of muscles & joints associated with

- simple backache
- strains
- bruises
- sprains

#### **Warnings**

For external use only.

**Do not apply to** wounds or damaged skin

#### **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**

arabica coffee oil, basil oil, cananga oil, carbomer homopolymer type C (allyl pentaerythritol crosslinked), cetostearyl alcohol, coconut oil, dimethicone, galbanum oil, glycerin, glyceryl monostearate, hyssop oil, lemon oil, methyl salicylate, nutmeg oil, palm oil, peppermint oil,

phenoxyethanol, picea mariana leaf oil, pine needle oil (pinus sylvestris) polyoxyl 20 cetostearyl ether, rosemary oil, sage oil, shea butter, sodium citrate, sunflower seed oil, tocopherol, water, white wax

**PRINCIPAL DISPLAY PANEL - 43g Jar Carton**

**Stressa™**

**back & neck  
pain relieving cream**

*for soothing relief  
of tense and sore  
muscles*

net wt. 1.5oz (43g)



**STRESSA BACK AND NECK PAIN RELIEVING**  
menthol cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53882-001
<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	1.25 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>white wax</b> (UNII: 7G1J5DA97F)	
<b>CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 4Q93RCW27E)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>coconut oil</b> (UNII: Q9L0O73W7L)	
<b>dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>lemon oil</b> (UNII: I9GRO824LL)	
<b>Nutmeg oil</b> (UNII: Z1CLM48948)	
<b>Peppermint oil</b> (UNII: AV092KU4JH)	
<b>PINE NEEDLE OIL (PINUS SYLVESTRIS)</b> (UNII: 5EXL5H740Y)	
<b>Rosemary oil</b> (UNII: 8LGU7VM393)	
<b>Sage oil</b> (UNII: U27K0H1H2O)	
<b>PICEA MARIANA LEAF OIL</b> (UNII: Q1J49L1A5O)	
<b>CANANGA OIL</b> (UNII: 8YOY78GNNX)	
<b>Basil oil</b> (UNII: Z129UMU8LE)	
<b>ARABICA COFFEE OIL</b> (UNII: IK55HKE887)	
<b>Galbanum oil</b> (UNII: 211UF7M8N1)	
<b>Hyssop oil</b> (UNII: 173D71924B)	
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
<b>palm oil</b> (UNII: 5QUO05548Z)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>shea butter</b> (UNII: K49155WL9Y)	
<b>sunflower oil</b> (UNII: 3W1JG795YI)	
<b>sodium citrate</b> (UNII: 1Q73Q2JULR)	
<b>tocopherol</b> (UNII: R0ZB2556P8)	
<b>water</b> (UNII: 059QF0KO0R)	

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53882-001-02	1 in 1 BOX		
1	NDC:53882-001-01	43 g in 1 JAR		
2	NDC:53882-001-04	1 in 1 BOX		
2	NDC:53882-001-03	85 g in 1 JAR		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	12/03/2012	

**Labeler** - Stressa Incorporated (031377428)**Establishment**

Name	Address	ID/FEI	Business Operations
Stressa Incorporated		031377428	MANUFACTURE(53882-001)

Revised: 12/2012

Stressa Incorporated