

**SANO TI AMO RELIEF AND REPAIR PAIN RELIEF- menthol, unspecified form, camphor (synthetic) cream**  
**Sano Ti Amo, LLC**

*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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**DRUG FACTS**

**NDC# 80216-111-02**

**Active Ingredients**

Camphor .3 %

Menthol 1.25%

**PURPOSE**

Topical Analgesic

Topical Analgesic

**USE** for the temporary relief of aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

**WARNINGS:**

- External Use Only
- Avoid contact with eyes, open cuts, damaged or irritated skin or sensitive areas.
- Do not use if allergic to any of the ingredients.

Those taking Coumadin (blood thinner or warfarin type medications) or have kidney issues/failure should consult their physician before using.

- Do not use with other topical products.
- Do not use if pregnant or nursing.
- Do not bandage.
- Do not apply heat.

Keep out of reach of children. If swallowed get medical help or contact Poison Control Center immediately.

**DIRECTIONS**

- Adults - 18 and over

- Apply and gently massage into painful joints and or muscles.
- Repeat as needed, no more than 4 times per day. Wash hands after each use.

## **OTHER INFORMATION**

\* Store at room temperature, protect from excessive heat

## **INACTIVE INGREDIENTS**

Water, Isopropyl Palmitate, Helianthus Annuus (Sunflower) Seed Oil, Stearyl Alcohol, Glycerine, Hetoxol C, Cetyl Alcohol, Gamma-aminobutyric Acid, Dimethyl Sulfone (MSM), Calendula Officinalis Flower Extract, Arnica Montana Flower Extract, Echinacea, Astragalus Propinquus Root, Phenoxyethanol, Ethylhexylglycerin, Mentha Piperita (Peppermint) Oil, Bacopa Monnieri Extract, Baptisia Tinctoria, Butyrospermum Parkii (Shea Butter), Hemp Seed Oil, Vitamin B6, Hemp Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil.

## **Questions & Comments:**

330-940-2129

[www.sanotiamo.com](http://www.sanotiamo.com)

Deerfield, Ohio 44411

## **Principal Display Panel - 2 oz Container Label**

SANO TI AMO LLC


Relief & Repair™

Pain Relief Cream

- Extra Strength
- Penetrates Quickly
- Fast & Long Lasting Relief
- 12 Restorative Botanicals
- Doctor Recommended

## **RELIEF FROM THE INSIDE OUT**

Net Wt. 2 oz. (60 ml)



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**DRUG FACTS**      NDC# 66902-111-02

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## SANO TI AMO RELIEF AND REPAIR PAIN RELIEF

menthol, unspecified form, camphor (synthetic) cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80216-111
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	13.4 mg in 1 mL
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	3.0 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ISOPROPYL PALMITATE</b> (UNII: 8CRQ2TH63M)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PPG-30 CETYL ETHER</b> (UNII: 00C2W8NVII)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>.GAMMA.-AMINOBUTYRIC ACID</b> (UNII: 2ACZ6IPC6I)	
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)	
<b>ECHINACEA PURPUREA FLOWERING TOP</b> (UNII: 2EMS3QFX65)	
<b>ECHINACEA PURPUREA ROOT</b> (UNII: OS64WTR4KU)	
<b>ECHINACEA ANGUSTIFOLIA ROOT</b> (UNII: D982V7VT3P)	
<b>ASTRAGALUS PROPINQUUS ROOT</b> (UNII: 922OP8YUPF)	
<b>BAPTISIA TINCTORIA</b> (UNII: 5K1UO2888Y)	
<b>BACOPA MONNIERI WHOLE</b> (UNII: DUB5K84ELI)	
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>ARNICA MONTANA</b> (UNII: O80TY208ZW)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>CANNABIS SATIVA SEED OIL</b> (UNII: 69VJ1LPN1S)	
<b>PYRIDOXINE</b> (UNII: KV2JZ1BI6Z)	
<b>CANNABIS SATIVA WHOLE</b> (UNII: B5ONF538PB)	
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80216-111-02	60 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/08/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/08/2019	

