# FASTRIN ACHES AND PAIN DEEP RELIEF- menthol, camphor cream Aidance Skincare & Topical Solutions, 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**

# **Active Ingredients**

Menthol 16%, Camphor 11%

## **Purpose**

Topical Analgesic

#### Uses

Temporarily relieves 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. **When using this product** - avoid contact with eyes or mucous membranes - do not bandage tightly or use with heating pad. **Stop use and ask a doctor if** - condition worsens or symptoms persist for more than 7 days - symptoms clear up and occur again within a few days - excessive skin irritation develops.

# Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

#### **Directions**

Adults and children 12 years and older: Massage ointment into affected area not more than 3 to 4 times daily. Children under 12 years of age: Ask a doctor.

#### **Inactive Ingredients**

Beeswax, Clove Oil, Cottonseed Oil, Distilled Water, Emulsifying Wax, Eucalyptus Oil, Jojoba Seed Oil, Magnesium Oxide, Peppermint Oil, Shea Butter, Silver Oxide, Sorbic Acid, Tea Tree Oil, Zinc Oxide

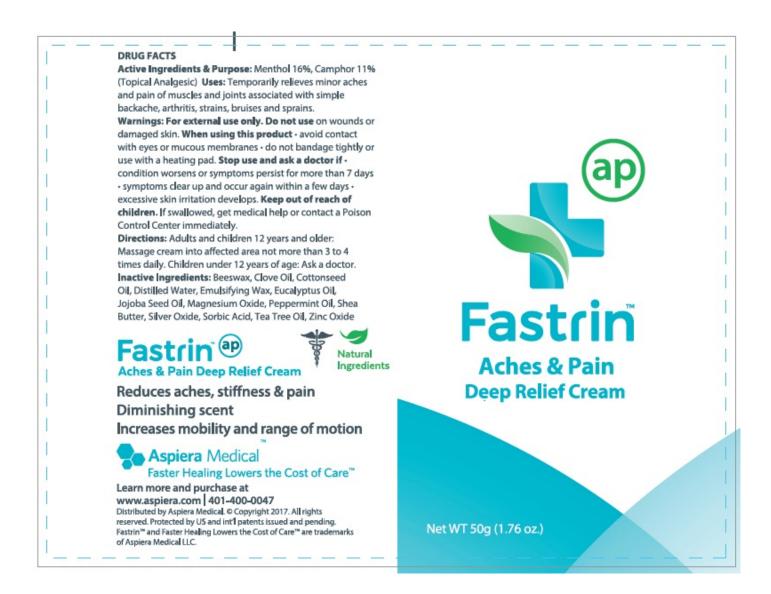
## PRINCIPAL DISPLAY PANEL - 50g Tube

#### **Fastrin**

Aches & Pain

Deep Relief Cream

Net WT 50g (1.76 oz.)



#### FASTRIN ACHES AND PAIN DEEP RELIEF

menthol, camphor cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-605
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	16 g in 100 g	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	11 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
CLOVE OIL (UNII: 578389 D6 D0)			

CORYMBIA CITRIODORA LEAF OIL (UNII: M63U6N96EB)	
COTTONSEED OIL (UNII: H3E878020N)	
JOJOBA OIL (UNII: 724GKU717M)	
MAGNESIUM O XIDE (UNII: 3A3U0 GI71G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SHEA BUTTER (UNII: K49 155WL9 Y)	
SILVER OXIDE (UNII: 897WUN6G6T)	
SORBIC ACID (UNII: X045WJ989B)	
TEA TREE OIL (UNII: VIF565UC2G)	
WATER (UNII: 059QF0KO0R)	
WHITE WAX (UNII: 7G1J5DA97F)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging				
	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
l	1 NDC:24909-605-10	10 g in 1 JAR; Type 0: Not a Combination Product	06/01/2017	
	2 NDC:24909-605-50	50 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2017	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	06/01/2017		

# **Labeler** - Aidance Skincare & Topical Solutions, LLC (018950611)

Establishment			
Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-605), label(24909-605)

Revised: 6/2017 Aidance Skincare & Topical Solutions, LLC