

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.

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.)

DRUG FACTS

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Fastrin^{ap}

Aches & Pain Deep Relief Cream

Reduces aches, stiffness & pain

Diminishing scent

Increases mobility and range of motion



Aspiera Medical

Faster Healing Lowers the Cost of Care[™]

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Natural
Ingredients



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: 578389D6D0)	

CORYMBIA CITRIODORA LEAF OIL (UNII: M63U6N96EB)
COTTONSEED OIL (UNII: H3E878020N)
JOJOBA OIL (UNII: 724GKU717M)
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)
PEPPERMINT OIL (UNII: AV092KU4JH)
POLYSORBATE 60 (UNII: CAL22UVI4M)
SHEA BUTTER (UNII: K49155WL9Y)
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	Marketing Start Date	Marketing End Date
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