ANALGESIC BALM- analgesic balm ointment Geritrex 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.

Analgesic Balm

Drug Facts

Menthol-6%, Methyl Salicylate-14% Purpose: External analgesic

Uses

For the temporary relief of minor aches and pain of muscles and joints.

Directions

Adults and children 2 years of age and older: Apply generously to affected area not more than 3 to 4 times daily. Children under 2 years of age: Consult a doctor.

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WARNINGS

Avoid contact with eyes or mucous membranes. Discontinue use if excessive irritation of the skin develops.

Do not: bandage tightly; apply to wounds, damaged skin, or use with a heating pad.
If condition worsens, or if symptoms persist more than 7 days or clear-up and reoccur again within a few days, discontinue use of this product and consult a doctor. If swallowed, get medical help or contact a Poison Control Center immediately.

INACTIVE INGREDIENT

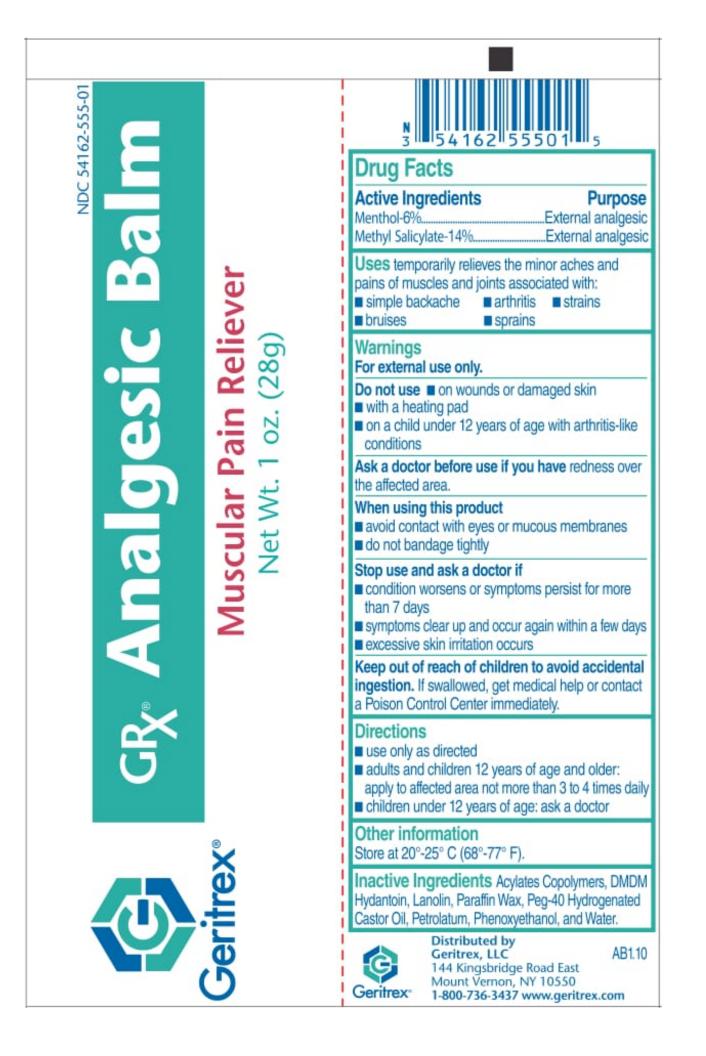
Acylates Copolymer, DMDM Hydantoin, Lanolin, Paraffin Wax, Peg-40 Hydrogenated Castor Oil, Petrolatum, Phenoxyethanol, Water.

STORAGE

At room temperature 20°-25° C (68°-77° F). Close cap tightly after use.

OTC - KEEP OUT OF REACH OF CHILDREN

Children under 2 years of age: Consult a doctor.



ANALGESIC BALM

analgesic balm ointment

Product Information	1					
Product T ype	HUMAN OTC D	DRUG Item (Item Code (Source)		NDC:54162-555	
Route of Administration	n TOPICAL					
Active Ingredient/A	ctive Moiety					
	Basis of	Strength	Strength			
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)			MENTHOL		1.74 g in 29 g	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ) METHYL SALICYLAT						
Inactive Ingredients	1					
Ingredient Name						
DMDM HYDANTO IN (UNI					Strength	
WATER (UNII: 059QF0KO	0 R)					
LANOLIN (UNII: 7EV65EA	AW6H)					
PARAFFIN (UNII: 1900E3F	H2ZE)					
POLYOXYL 40 HYDROG	GENATED CASTOR OIL (UN	NII: 7YC686GQ8F)				
PETROLATUM (UNII: 4T6	H12BN9U)					
PHENOXYETHANOL (UN	II: HIE492ZZ3T)					
CARBOMER COPOLYME	ER TYPE A (UNII: 71DD5V99	5L)				
Packaging						
# Item Code	Package Descr	ription	Marketing Start Dat	e Marke	ting End Dat	
1 NDC:54162-555-01 29	g in 1 TUBE; Type 0: Not a Co	ombination Product	07/31/2015			
Marketing Inform	mation					
Marketing Category	Application Number or	Monograph Citation	Marketing Start D	ate Mark	eting End Dat	

Labeler - Geritrex LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
Geritrex LLC		112796248	manufacture(54162-555)