

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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more than 3 to 4 times daily.
Children under 2 years of age:
Consult a doctor.

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.

NDC 54162-555-01

GR^x Analgesic Balm

Muscular Pain Reliever

Net Wt. 1 oz. (28g)



Geritrex[®]



Drug Facts

Active Ingredients	Purpose
Menthol-6%	External analgesic
Methyl Salicylate-14%	External analgesic

Uses temporarily relieves the minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only.

- Do not use**
- on wounds or damaged skin
 - with a heating pad
 - on a child under 12 years of age with arthritis-like conditions

Ask a doctor before use if you have redness over the affected area.

When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly

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 occurs

Keep out of reach of children to avoid accidental ingestion. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- use only as directed
- adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

Other information

Store at 20°-25° C (68°-77° F).

Inactive Ingredients Acylates Copolymers, DMDM Hydantoin, Lanolin, Paraffin Wax, Peg-40 Hydrogenated Castor Oil, Petrolatum, Phenoxyethanol, and Water.



Distributed by
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ANALGESIC BALM

analgesic balm ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-555
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.74 g in 29 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	4.06 g in 29 g

Inactive Ingredients

Ingredient Name	Strength
DMDM HYDANTOIN (UNII: BYR0546TOW)	
WATER (UNII: 059QF0K00R)	
LANOLIN (UNII: 7EV65EAW6H)	
PARAFFIN (UNII: I9O0E3H2ZE)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
PETROLATUM (UNII: 4T6H12BN9U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-555-01	29 g in 1 TUBE; Type 0: Not a Combination Product	07/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/09/2012	

Labeler - Geritrex LLC (112796248)

Establishment

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