KERATEK- menthol, methyl salicylate gel
GERITREX CORP

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.

KERATEK GEL

DRUG FACTS

Active Ingredients	Purpose
Menthol 16%	Topical analgesic
Methyl Salicylate 28%	Topical analgesic

USES

Temporarily retieves the minor aches and pains of muscles and joints associated with single backache, arthritis, strains, bruises and sprains.

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

Warnings

For external use only

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

Ask 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

symtoms clear up and occur again within a few days

excessive skin irritation occurs

Inactive Ingredients

Arnica, carbomer, cetyl alcohol, dmdm hydantoin, edetate disodium, lanolin, methyl paraben, paraffin wax, peg 40 hydrogenated castor oil,

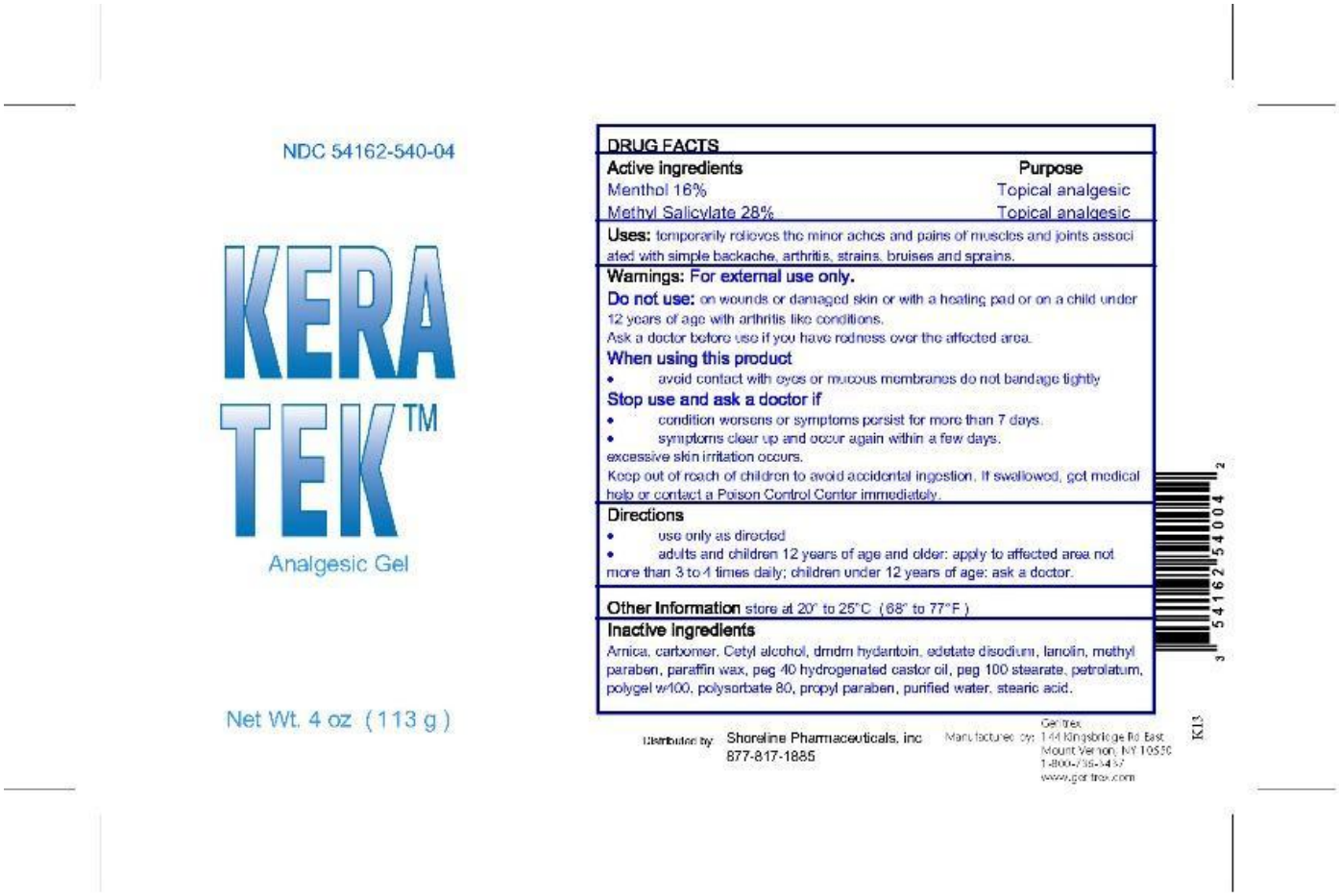
peg 100 stearate, petrolatum, polygel w400, polysorbate 80, propyl paraben, purified water, stearic acid.

Keep out of reach of children to avoid accidental ingestion. if swallowed, get medical help or

contact a Poison Control Center Immediately

Store at 20' to 25'C (68' to 77'F)

Apply to affected area not more than 3 to 4 times daily.



KERATEK

menthol, methyl salicylate gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54162-540
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
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	28 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
ARNICA MONTANA (UNII: O80TY208ZW)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	

EDETATE DISODIUM (UNII: 7FLD91C86K)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-540-04	113 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/21/2013	

Labeler - GERITREX CORP (112796248)

Registrant - GERITREX CORP (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
GERITREX CORP		112796248	manufacture(54162-540)

Revised: 10/2013 GERITREX CORP