MENTHOL AND METHYL SALICYLATE- electric medicated balm ultra strength ointment
FEI FAH MEDICAL MANUFACTURING PTE LTD

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%
Methyl salicylate 32%

Purpose
External analgesic
External analgesic

Uses
For the temporary relief of minor aches and pains of muscles and joints due to
simple backache
arthritis
strains
bruises
sprains

Warnings
For external use only

Do not use
on wounds
on irritated or damaged skin
on the face
otherwise than as directed

When using this product
avoid contact with the eyes or mucous membranes
do not bandage tightly

Stop use and ask a doctor if
condition worsens
symptoms persist for more than 7 days
symptoms clear up and occur again within a few days
excessive irritation of the skin develops
nausea, vomiting, abdominal discomfort, diarrhea, or skin rash occurs
when using for pain of arthritis
pain persists for more than 10 days
redness is present
in conditions affecting children under 12 years of age

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

Directions
Adults and children 3 years of age and older: Apply a small amount with your finger tip then gently rub into the affected area not more than 3 to 4 times daily.
Children under 3 years of age: Do not use, consult your doctor.

Other information
keep container tightly closed
store at 15° to 30°C (59° to 86°F)

Inactive ingredients
Petrolatum

Questions or comments? (888) 221-3496 M-F 9am to 5pm
you may also report serious side effects to this phone number

ELECTRIC MEDICATED BALM
External Analgesic
NDC 63299-001-01
NET 2.45 oz (70g)

MENTHOL AND METHYL SALICYLATE

electric medicated balm ultra strength ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63299-001
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	32 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63299-001-01	1 in 1 BOX	03/28/2018	
1		70 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:63299-001-02	1 in 1 BOX	03/28/2018	
2		10 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/28/2018	

Labeler - FEI FAH MEDICAL MANUFACTURING PTE LTD (628416141)

Establishment

Name	Address	ID/FEI	Business Operations
FEI FAH MEDICAL MANUFACTURING PTE LTD		628416141	manufacture(63299-001)

Revised: 3/2018 FEI FAH MEDICAL MANUFACTURING PTE LTD