IMADA FOUR SEASONS SAFE ANALGESIC BALM- menthol oil LUEN WAH HK MEDICINE 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%

Purpose

External Analgesic

Uses

Temporarily relieves minor aches, muscles and joint pains due to:

- simple backache
- arthritis
- strains
- sprains
- bruises
- neck
- shoulder
- stiff and sore muscles

Warnings

- Dexternal use only
- use only as directed

Do not use

- Ion opened wounds
- on damaged skin

When using this product

- Davoid contact with the eyes
- do not bandage tighly

Stop use and ask a doctor if

- Da rash or irritation develops
- condition worsens
- symptoms persist for more than 7 days or clears up and occur again within a few days

□If pregnant or breast-feeding, □ ask a health professional before use

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

Directions

- □adults and children 12 years and older, apply to affected area, and massage gently not more than 3-4 times daily
- children under 12 years of age, consult a doctor before using

Other information

- Istore at room temperature
- close tightly after used

□ □ Inactive ingredients

peppermint oil, cassia oil, clove oil, cinnamon leaf oil, licorice



IMADA FOUR SEASONS SAFE ANALGESIC BALM

menthol oil

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63041-110
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 mL	

Inactive Ingredients			
Ingredient Name	Strength		
PEPPERMINT O IL (UNII: AV092KU4JH)			
PADANG CASSIA O IL (UNII: 0 E 15252 LIW)			
CLOVE OIL (UNII: 578389 D6 D0)			
CINNAMON LEAF OIL (UNII: S92U8SQ71V)			
LICORICE (UNII: 61ZBX54883)			

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63041-110- 01	25 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/30/2014	06/30/2020	
2	NDC:63041-110- 02	2 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/30/2014	06/30/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	10/30/2014	06/30/2020	

Labeler - LUEN WAH HK MEDICINE LTD (666091871)

Establishment				
Name	Address	ID/FEI	Business Operations	
LUEN WAH HK MEDICINE LTD		666091871	manufacture(63041-110)	

Revised: 11/2019 LUEN WAH HK MEDICINE LTD