QUALI HERBAL- menthol, methyl salicylate patch Teh Seng Pharmaceutical Mfg. Co., 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.

Teh Seng Pharmaceutical Mfg. Co., Ltd

ACTIVE INGREDIENTS

Menthol 10%

Methyl Salicylate 0.5%

Purpose

Menthol Topical Analgesic

Methyl Salicylate Topical Analgesic

Uses

For temporary relief of minor aches and pains of muscles and joints associated with:

Simple backache

Arthritis

Sprains

Strains

Bruises

Warnings

- 1. For external use only. Avoid applying around the eyes and mucous membranes, or open wounds.
- 2. Pregnant women, nursing mothers and any person with allergic reactions to drugs or cosmetics should consult physician before use. Children should use this product under supervision.

Stop Use

Discontinue if skin irritation develops.

Keep Out Of Reach of Children.

Keep out of reach of children.

Directions

- 1. Clean and dry the affected areas before application.
- 2. Remove the protective film while applying the areas 1-2 times daily, cut into smaller size if desired. If necessary up to 3 sheets per day.
- 3. Use only as directed. Firmly affix with adhesive tapes or elastic bandages around joint areas to secure the patch if needed.

Storage

Store at room temperature away from direct sunlight. Properly sealed to remain fresh.

Inactive Ingredients

ANGELICA SINENSIS ROOT, ANGELICA DAHURICA WHOLE, ALMOND, SCROPHULARIA NINGPOENSIS ROOT, GLEDITSIA SINENSIS WHOLE, LIQUIDAMBAR FORMOSANA RESIN, ALLIUM FISTULOSUM WHOLE, TURPENTINE, FRANKINCENSE, MYRRH, YELLOW WAX, ROSIN, ZINC OXIDE, SESAME OIL

U.S. Sole Agent

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Drug Facts

QUALIPATCH NDC 67536-882-01

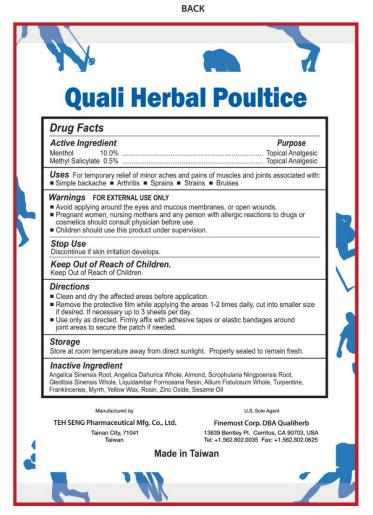
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QUALIPATCH

QUALIPATCH

OUR PATCH

OUR



QUALI HERBAL

menthol, methyl salicylate patch

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67536-882	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	10 g in 100 g		
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.5 g in 100 g		

Inactive Ingredients		
Ingredient Name	Strength	
ANGELICA SINENSIS ROOT (UNII: B66F4574UG)		
ANGELICA DAHURICA WHO LE (UNII: 667W6C5J4P)		
ALMOND (UNII: 3Z252A2K9G)		
SCROPHULARIA NINGPOENSIS ROOT (UNII: HC0FB6P85R)		
GLEDITSIA SINENSIS WHOLE (UNII: FS3UB95UTG)		
LIQUIDAMBAR FORMOSANA RESIN (UNII: 597LBL467J)		
ALLIUM FISTULO SUM WHOLE (UNII: 51BV41D79A)		
TURPENTINE (UNII: XJ6RUH0O4G)		
FRANKINCENSE (UNII: R9 XLF1R1WM)		
MYRRH (UNII: JC71GJ1F3L)		
YELLOW WAX (UNII: 2ZA36H0S2V)		
ROSIN (UNII: 88S87KL877)		
ZINC OXIDE (UNII: SOI2LOH54Z)		
SESAME OIL (UNII: QX10 HYY4QV)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:67536-882-01	100 in 1 BOX	10/10/2013		
1	16 g in 1 PACKET; 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	10/10/2013			

Labeler - Teh Seng Pharmaceutical Mfg. Co., Ltd (656347721)