QUALI COLD- menthol 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

Methyl Salicylate 2.0%

Menthol 1.0% Camphor 0.5%

Purpose

Methyl Salicylate Topical Analgesic

Menthol Topical Analgesic

Camphor 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

Phellodendron Amurense Whole

U.S. Sole Agent

Finemost Corp., Qualiherb

Cerritos, Ca 90703

Tel: (562)802-0035

Fax: (562)802-0625

Made in Taiwan

Drug Facts

QUALI PATCH NDC 67536-881-01

C.G.M.P

QUALI PATCH (COLD)



QUALI COLD

menthol patch

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67536-884 | |
| Route of Administration | TOPICAL | | | |

| Active Ingredient/Active Moiety | | |
|--|------------------------|-------------------|
| Ingredient Name | Basis of Strength | Strength |
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) | METHYL SALICYLATE | 2 g in 100 g |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 1 g in 100 g |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET) | CAMPHOR (SYNTHETIC) | 0.5 g in 100 g |

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| PHELLO DENDRO N AMURENSE WHO LE (UNII: 30 ZN5NGR9 L) | |

| ı | Packaging | | | | |
|---|--------------------|---|-----------------------------|--------------------|--|
| l | # Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| ı | 1 NDC:67536-884-01 | 100 in 1 BOX | 10/10/2013 | | |
| l | 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 | | |
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Labeler - Teh Seng Pharmaceutical Mfg. Co., Ltd (656347721)

Revised: 10/2016 Teh Seng Pharmaceutical Mfg. Co., Ltd