

QUALI WARM- 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 3.0%

Methyl Salicylate 0.8%

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.

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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

Ginger, Gelatin, Frankincense, Myrrh, Rosin, Turpentine, Zinc Oxide

U.S. Sole Agent

Finemost Corp., Qualiherb

Cerritos, Ca 90703

Tel: (562)802-0035

Fax: (562)802-0625

Made in Taiwan

Drug Facts

FRONT	BACK																						
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;"> <p>QUALI PATCH</p> <p>QUALI PATCH (WARM)</p> <p>C.G.M.P</p> </div> <div style="text-align: right;"> <p>NDC 67536-883-01</p> </div> </div>	<div style="text-align: center; margin-bottom: 10px;"> <p>QUALI PATCH (WARM)</p> </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2">Drug Facts</td> </tr> <tr> <td style="text-align: left;">Active Ingredient</td> <td style="text-align: right;">Purpose</td> </tr> <tr> <td>Menthol 3.0%</td> <td style="text-align: right;">Topical Analgesic</td> </tr> <tr> <td>Methyl Salicylate 0.8%</td> <td style="text-align: right;">Topical Analgesic</td> </tr> <tr> <td colspan="2"> <p>Uses For temporary relief of minor aches and pains of muscles and joints associated with: ■ Simple backache ■ Arthritis ■ Sprains ■ Strains ■ Bruises</p> </td> </tr> <tr> <td colspan="2"> <p>Warnings FOR EXTERNAL USE ONLY</p> <ul style="list-style-type: none"> ■ Avoid applying around the eyes and mucous membranes, or open wounds. ■ 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. </td> </tr> <tr> <td colspan="2"> <p>Stop Use Discontinue if skin irritation develops.</p> </td> </tr> <tr> <td colspan="2"> <p>Keep Out of Reach of Children. Keep Out of Reach of Children.</p> </td> </tr> <tr> <td colspan="2"> <p>Directions</p> <ul style="list-style-type: none"> ■ Clean and dry the affected areas before application. ■ 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. ■ Use only as directed. Firmly affix with adhesive tapes or elastic bandages around joint areas to secure the patch if needed. </td> </tr> <tr> <td colspan="2"> <p>Storage Store at room temperature away from direct sunlight. Properly sealed to remain fresh.</p> </td> </tr> <tr> <td colspan="2"> <p>Inactive Ingredient Ginger, Gelatin, Frankincense, Myrrh, Rosin, Turpentine, Zinc Oxide.</p> </td> </tr> </table> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="text-align: center;"> <p><small>Manufactured by</small></p> <p>TEH SENG Pharmaceutical Mfg. Co., Ltd.</p> <p><small>Tainan City, 71041 Taiwan</small></p> </div> <div style="text-align: center;"> <p><small>U.S. Sole Agent</small></p> <p>Finemost Corp. DBA Qualiherb</p> <p><small>13839 Bentley Pl. Cerritos, CA 90703, USA Tel: +1.562.802.0035 Fax: +1.562.802.0625</small></p> </div> </div> <p style="text-align: center; margin-top: 10px;">Made in Taiwan</p>	Drug Facts		Active Ingredient	Purpose	Menthol 3.0%	Topical Analgesic	Methyl Salicylate 0.8%	Topical Analgesic	<p>Uses For temporary relief of minor aches and pains of muscles and joints associated with: ■ Simple backache ■ Arthritis ■ Sprains ■ Strains ■ Bruises</p>		<p>Warnings FOR EXTERNAL USE ONLY</p> <ul style="list-style-type: none"> ■ Avoid applying around the eyes and mucous membranes, or open wounds. ■ 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. 		<p>Stop Use Discontinue if skin irritation develops.</p>		<p>Keep Out of Reach of Children. Keep Out of Reach of Children.</p>		<p>Directions</p> <ul style="list-style-type: none"> ■ Clean and dry the affected areas before application. ■ 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. ■ Use only as directed. Firmly affix with adhesive tapes or elastic bandages around joint areas to secure the patch if needed. 		<p>Storage Store at room temperature away from direct sunlight. Properly sealed to remain fresh.</p>		<p>Inactive Ingredient Ginger, Gelatin, Frankincense, Myrrh, Rosin, Turpentine, Zinc Oxide.</p>	
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QUALI WARM

menthol, methyl salicylate patch

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:67536-883

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.8 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GINGER (UNII: C5529G5JPQ)	
GELATIN (UNII: 2G86QN327L)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
MYRRH (UNII: JC71GJ1F3L)	
ROSIN (UNII: 88S87KL877)	
TURPENTINE (UNII: XJ6RUH0O4G)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67536-883-01	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)

Revised: 10/2016

Teh Seng Pharmaceutical Mfg. Co., Ltd