

## **MEN-PHOR- menthol, camphor lotion**

**Geritrex LLC**

*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.*

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### **Men-Phor**

#### **Drug Facts**

Active Ingredients Purpose

0.5% Camphor . . . .Anti-Infective, Anti-Pruritic

0.5% Menthol . . . .Anti-Pruritic

#### **Uses**

To provide temporary relief for dry itching skin, sunburn, insect bites and pruritus.

#### **Directions**

- Apply two or three times daily, or as directed by your physician.

#### **Warnings**

##### **For External Use Only**

- Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.
- If improvement does not occur, or condition worsens after regular use as directed, discontinue use and consult a physician.
- Do not use on children under two years of age.
- Do not apply under compresses or bandages

#### **Other Ingredient**

Alcohol, Carbomers, Cetyl Alcohol, DMDM Hydantoin, Fragrance, Glycerin, Glycol Stearate, Methylparaben, PEG-200 Dilaurate, PEG-40 Hydrogenated Castor Oil, Petrolatum, Propylparaben, Stearic Acid, Trolamine, Water

Keep out of reach of children

Apply two or three times daily.

NDC 54162-550-02



# Men-Phor<sup>TM</sup> Anti-Itch Lotion

**STEROID FREE**

Comparable to SARNA Lotion\*

**Cools & Relieves Itching**

**Effective for:**

- Sunburn • Poison Ivy
- Poison Oak • Insect Bites

2 FL. OZ. (59mls)

\* Registered trademark of Stiefel Laboratories



541625500217

### Drug Facts

Active Ingredients	Purpose
0.5% Camphor.....	Anti-Itchive, Anti-Pruritic
0.5% Menthol.....	Anti-Pruritic

**Uses** for the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites, minor skin irritations and rashes due to poison ivy/oak/sumac

#### Warnings

**FOR EXTERNAL USE ONLY**

When using this product ■ avoid contact with the eyes.

Stop use and ask a doctor if ■ condition worsens ■ symptoms persist for more than 7 days or clear up and occur again within a few days.

**KEEP OUT OF REACH OF CHILDREN.** If swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

**Adults and children 2 years of age and older:**

■ apply thin layer to affected skin area only up to 4 times daily. Do not use on broken, reddened and swollen skin. ■ avoid nostrils and mouth ■ rinse well with water in case of accidental contact with eyes ■ do not apply to large areas of the body ■ if irritation or allergic reaction occurs (rash, reddening, pain, itchiness, burning sensation, blistering or swelling) consult a doctor ■ do not use if you are allergic to camphor, menthol or any of the ingredients

**Children under 2 years of age:** consult a doctor. Do not use around the nostrils of babies or infants.

#### Other information

Store at or below 15°-30°C (59°-86°F). Check with your doctor if you are planning to become pregnant or breast-feeding.

**Inactive ingredients** Alcohol, Carbomers, Cetyl Alcohol, DMDM Hydantoin, Fragrance, Glycerin, Glycol Stearate, Methylparaben, PEG-200 Dilaurate, PEG-40 Hydrogenated Castor Oil, Petrolatum, Propylparaben, Stearic Acid, Trolamine, Water

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NDC 54162-550-09



# Men-Phor<sup>TM</sup> Anti-Itch Lotion

**STEROID FREE**

Comparable to SARNA Lotion\*

**Cools & Relieves Itching**

**Effective for:**

- Sunburn • Poison Ivy
- Poison Oak • Insect Bites

7.5 FL. OZ. (222mls)

\* Registered trademark of Stiefel Laboratories



541625500916

### Drug Facts

Active Ingredients	Purpose
0.5% Camphor.....	Anti-Itchive, Anti-Pruritic
0.5% Menthol.....	Anti-Pruritic

**Uses** for the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites, minor skin irritations and rashes due to poison ivy/oak/sumac

#### Warnings

**FOR EXTERNAL USE ONLY**

When using this product ■ avoid contact with the eyes.

Stop use and ask a doctor if ■ condition worsens

■ symptoms persist for more than 7 days or clear up and occur again within a few days.

**KEEP OUT OF REACH OF CHILDREN.**

If swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

**Adults and children 2 years of age and older:**

■ apply thin layer to affected skin area only up to 4 times daily. Do not use on broken, reddened and swollen skin. ■ avoid nostrils and mouth ■ rinse well with water in case of accidental contact with eyes ■ do not apply to large areas of the body ■ if irritation or allergic reaction occurs (rash, reddening, pain, itchiness, burning sensation, blistering or swelling) consult a doctor ■ do not use if you are allergic to camphor, menthol or any of the ingredients

**Children under 2 years of age:** consult a doctor. Do not use around the nostrils of babies or infants.

#### Other information

Store at or below 15°-30°C (59°-86°F). Check with your doctor if you are planning to become pregnant or breast-feeding.

**Inactive ingredients** Alcohol, Carbomers, Cetyl Alcohol, DMDM Hydantoin, Fragrance, Glycerin, Glycol Stearate, Methylparaben, PEG-200 Dilaurate, PEG-40 Hydrogenated Castor Oil, Petrolatum, Propylparaben, Stearic Acid, Trolamine, Water

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MP7.5DC.10

NDC 54162-550-07



# Men-Phor<sup>TM</sup> Anti-Itch Lotion

**STERIOD FREE**

Comparable to SARNA Lotion\*

**Cools & Relieves Itching**

Effective for:

- Sunburn • Poison Ivy
- Poison Oak • Insect Bites

7.5 FL. OZ. (222mls)

\* Registered trademark of Stiefel Laboratories



<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
0.5% Camphor.....	Anti-Infective, Anti-Pruritic
0.5% Menthol.....	Anti-Pruritic
<b>Uses</b> for the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites, minor skin irritations and rashes due to poison ivy/oak/sumac	
<b>Warnings</b>	
<b>FOR EXTERNAL USE ONLY</b>	
When using this product ■ avoid contact with the eyes.	
Stop use and ask a doctor if ■ condition worsens	
■ symptoms persist for more than 7 days or clear up and occur again within a few days.	
<b>KEEP OUT OF REACH OF CHILDREN.</b>	
If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
■ To open, squeeze cap tightly and turn pump counter-clockwise.	
<b>Adults and children 2 years of age and older:</b>	
■ apply thin layer to affected skin area only up to 4 times daily. Do not use on broken, reddened and swollen skin.	
■ avoid nostrils and mouth	
■ rinse well with water in case of accidental contact with eyes	
■ do not apply to large areas of the body	
■ if irritation or allergic reaction occurs (rash, reddening, pain, itchiness, burning sensation, blistering or swelling) consult a doctor	
■ do not use if you are allergic to camphor, menthol or any of the ingredients	
<b>Children under 2 years of age:</b> consult a doctor. Do not use around the nostrils of babies or infants.	
<b>Other information</b>	
Store at or below 15°-30°C (59°-86°F). Check with your doctor if you are planning to become pregnant or breast-feeding.	
<b>Inactive ingredients</b> Alcohol, Carbomers, Cetyl Alcohol, DMDM Hydantoin, Fragrance, Glycerin, Glycol Stearate, Methylparaben, PEG-200 Dilaurate, PEG-40 Hydrogenated Castor Oil, Petrolatum, Propylparaben, Stearic Acid, Trolamine, Water	
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<b>MEN-PHOR</b>			
menthol, camphor lotion			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54162-550
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.11 g in 222 mL
	CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	1.11 g in 222 mL
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>
	WATER (UNII: 059QF0K00R)		
	ALCOHOL (UNII: 3K9958V90M)		
	STEARIC ACID (UNII: 4ELV7Z65AP)		
	CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)		
	CETYL ALCOHOL (UNII: 936JST6JCN)		
	DMDM HYDANTOIN (UNII: BYR0546TOW)		
	GLYCOL STEARATE (UNII: 0324G66D0E)		

PEG-200 DILAURATE (UNII: TWV5J70L88)

PEG-40 CASTOR OIL (UNII: 4ERD2076EF)

PETROLATUM (UNII: 4T6H12BN9U)

METHYLPARABEN (UNII: A2I8C7HI9T)

PROPYLPARABEN (UNII: Z8IX2SC1OH)

TROLAMINE (UNII: 9O3K93S3TK)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-550-07	222 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/31/2015	
2	NDC:54162-550-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2015	
3	NDC:54162-550-09	222 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/31/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/31/2015	

**Labeler** - Geritrex LLC (112796248)

### Establishment

Name	Address	ID/FEI	Business Operations
Geritrex LLC		112796248	manufacture(54162-550)

Revised: 1/2018

Geritrex LLC