

MAJOR CAMPHOR AND PHENOL - antiseptic liquid

Major Pharmaceuticals

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 ingredient

Camphorated phenol

(camphor, 10.8% and phenol, 4.7%)

☐Purpose

Pain reliever/antiseptic

☐USES

- first aid to help reduce the risk of infection associated with minor cuts, scrapes, minor burns, and insect bites
- for the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, fever blisters and cold sores

☐Warnings

- for external use only

☐Do not use

- in the eyes
- or apply over large areas of the body

☐Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

☐When using this product

- avoid contact with the eyes
- do not bandage

☐Stop use and ask 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. **☐Do not induce vomiting☐** before contacting medical help or a Poison Control Center

Directions

- clean the affected area
- adults and children 2 years of age or older: apply a small amount of this product on the area 1 to 3 times daily
- children under 2 years of age: consult a doctor

Inactive ingredients

eucalyptus oil, light mineral oil

Major

Camphor & Phenol

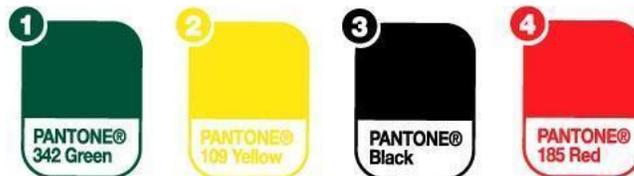
Antiseptic Liquid

1.5 fl. oz (44ml)

label image

10.8X3.5CM

<p>Drug Facts Active Ingredients: Camphorated phenol (camphor, 10.8% and phenol, 4.7%) Uses • first aid to help reduce the risk of infection associated with minor cuts, scrapes, and minor burns • for the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites, fever blisters and cold sores Warnings • for external use only Do not use • in the eyes • over large areas of the body Ask a doctor before use if you have • deep or puncture wounds • animal bites • serious burns When using this product • avoid contact with the eyes • do not bandage <small>Distributed by: Major Pharmaceuticals, 31778 Enterprise Drive, Livonia, MI 48150 / M-109</small></p>	<p>MAJOR  NDC 00904-7851-75 Camphor & Phenol Antiseptic Liquid INSTANT PAIN RELIEF Stops Pain and Itching Starts Healing 1.5 FL OZ (44 mL)</p>	<p>Drug Facts (continued) Stop use and ask 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. Do not induce vomiting before contacting medical help or a Poison Control Center Directions • clean the affected area • adults and children 2 years of age or older: apply directly to the affected area 1 to 3 times daily • children under 2 years of age: consult a doctor <small>Serious Adverse Effects Call: (800) 616-2471 1616800, Rev. 3/08 Re-order No.700640</small></p>
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Major

Camphor & Phenol

Antiseptic Liquid

1.5 fl. oz (44ml)

carton image



MAJOR®

Drug Facts

Active ingredients

Camphorated phenol (camphor, 10.8% and phenol, 4.7%) Pain reliever/ antiseptic

Purpose

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Drug Facts (continued)

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- serious burns

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Inactive ingredients

eucalyptus oil, light mineral oil

MAJOR®

Camphor & Phenol

Antiseptic Liquid

INSTANT PAIN RELIEF

Stops Pain and Itching; Starts Healing:

**SORES • CUTS
BURNS • INSECT BITES
FEVER BLISTERS
COLD SORES**

*Compare to the active ingredients of CAMPHO PHENIQUE®

1.5 FL OZ (44 mL)

Stops hurting. Starts healing. Fights infection. Helps stop pain and itch. Forms a soothing, germ-killing shield to help speed healing of:

- cold sores, fever blisters
- cuts, minor burns, blisters, abrasions, scrapes
- razor nicks, chafed or irritated skin
- itchy bites from chiggers, mosquitoes, sand fleas and black flies.

*This product is not manufactured or distributed by Bayer Corporation owner of the registered trademark Campho-Phenique®.

Serious Adverse Effects Call (800) 616-2471.

Distributed by: Major Pharmaceuticals
31778 Enterprise Drive, Livonia, MI 48158
Reorder # 700640



EXPIRES

LOT NO.

Cat. No. 0309-000
1516800
Rev. 3/08
M-109



MAJOR CAMPHOR AND PHENOL

antiseptic liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:00904-7851
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	10.8 g in 100 mL
PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)	PHENOL	4.7 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
EUCALYPTUS OIL (UNII: 2R04ONI662)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:00904-7851-6	1 in 1 CARTON		
1	NDC:00904-7851-7	44 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	05/09/2008	

Labeler - Major Pharmaceuticals (191427277)

Registrant - Lee Pharmaceuticals (056425432)

Establishment

Name	Address	ID/FEI	Business Operations
Major Pharmaceuticals		191427277	label(00904-7851)

Establishment

Name	Address	ID/FEI	Business Operations
Lee Pharmaceuticals		056425432	pack(00904-7851) , manufacture(00904-7851)