CAMPHO-PHENIQUE ANTISEPTIC- camphor (synthetic) and phenol gel Foundation Consumer Healthcare

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.

Campho-Phenique® Antiseptic Gel

Drug Facts

Active ingredient

Camphorated phenol (camphor 10.8% and phenol 4.7%)

Purposes

Pain reliever/antiseptic

Uses

- for temporary relief of pain and itching associated with
 - minor burns
 - sunburn
 - minor cuts
 - scrapes
 - insect bites
 - minor skin irritation
- first aid to help protect against infection in
 - minor cuts
 - scrapes
 - burns

Warnings

For external use only

Do not use

- over large areas of the body
- with a bandage

Ask a doctor before use if you have

- a deep or puncture wound
- animal bites
- serious burns

When using this product do not use in or near the eyes. If contact occurs, rinse

eyes thoroughly with water and obtain medical attention.

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.

Do not induce vomiting before contacting medical help or a Poison Control Center.

Directions

- adults and children 2 years of age and over:
 - clean the affected area
 - apply a small amount of this product on the area 1 to 3 times daily
 - do not bandage
- children under 2 years of age: ask a doctor

Other information

- store at room temperature. Avoid excessive heat above 40°C (104°F).
- close cap tightly after use

Inactive ingredients

light mineral oil, colloidal silicon dioxide, aloe barbadensis leaf extract, glycerin, eucalyptus oil

Questions or comments?

1-855-602-2676 weekdays 9 AM to 5 PM EST

Distributed by: Foundation Consumer Healthcare, LLC. Pittsburgh, PA 15212

PRINCIPAL DISPLAY PANEL - 14 g Tube Carton

with aloe

MAXIMUM STRENGTH

MEDICATED CAMPHO PHENIQUE®

PAIN & ITCH RELIEF ANTISEPTIC GEL

Multi-purpose formula insect bites | minor burns | cuts, scrapes & irritations Helps prevent infection NET WT 0.5 OZ (14 g)

Cold Sore Treatment try Campho Phenique® of cold sore symptoms, For specific treatment



Drug Facts (continued)

Other information

■ do not bandage

Directions

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ANTISEPTIC GEL PAIN & ITCH RELIEF

Campho Phenique® combines Camphor and Phenol to deliver pain-relieving, anti-itch and antiseptic actions



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Distributed by: Filtsburgh, PA 15212 OSOSO

NET WT 0.5 OZ (14 g)

Helps prevent infection

insect bites | minor burns | cuts, scrapes & irritations

ANTISEPTIC GEL

PAIN & ITCH RELIEF





CAMPHO PHENIQUE

MEDICATED

MAXIMUM STRENGTH



CAMPHO-PHENIQUE ANTISEPTIC

camphor (synthetic) and phenol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69536-109

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 g		
Phenol (UNII: 339NCG44TV) (Phenol - UNII:339NCG44TV)	Phenol	4.7 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
Silicon Dioxide (UNII: ETJ7Z 6XBU4)			
Eucalyptus Oil (UNII: 2R04ONI662)			
Glycerin (UNII: PDC6A3C0OX)			
Light Mineral Oil (UNII: N6K5787QVP)			
Aloe Vera Leaf (UNII: ZY81Z83H0X)			

F	Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:69536-109- 50	1 in 1 CARTON	11/15/2021			
1		14 g in 1 TUBE; 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	11/15/2021			

Labeler - Foundation Consumer Healthcare (079675882)

Revised: 11/2021 Foundation Consumer Healthcare