

MERTHIOLATE- benzalkonium chloride cream
World Perfumes, Inc

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.

Active Ingredients	Purpose
Benzalkonium Chloride 0.13%	First Aid Antiseptic

Use first aid to help prevent skin infection in

- minor cuts
- scrapes
- burns

☐**Keep out of the reach of children.**☐ If swallowed, get medical help or contact a Poison Control Center right away.

Merthiolate Tincture

Mercury Free

First Aid Antiseptic

For External Use Only

☐**Directions**

- clean the affected area
- apply a small amount on the area 1 to 3 times daily
- may be covered by a sterile bandage
- if bandaged, let dry first

☐**Warnings**

- ☐For external use only
- Ask a doctor before use if you have deep or puncture wounds, animal bites or serious burns.
- When using this product
- do not use in eyes or apply over large areas of the body
- do not use longer than 1 week unless directed by a doctor
- Stop use and ask a doctor if condition persists or gets worse

☐**Inactive Ingredients**☐ alcohol, acetone, purified water, FD&C red #22

GM **GERMA®**
MERTHIOLATE
TINCTURE
MERCURY FREE
FIRST AID ANTISEPTIC
FOR EXTERNAL USE ONLY
CONTAINS 1 Fl. Oz. (29.62ml.)

Distributed by: **Germa Products, Inc.**
 Miami, Florida 33186 / www.germa.net

Drug Facts

Active Ingredients
 Benzalkonium Chloride 0.13% **Purpose**
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Directions ■ clean the affected area ■ apply a small amount on the area 1 to 3 times daily ■ may be covered with a sterile bandage ■ if bandaged, let dry first.

Other information product will stain skin and clothing.

Inactive Ingredients: alcohol, acetone, purified water, FD&C red #22.

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MERTHIOLATE

benzalkonium chloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10095-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ACETONE (UNII: 1364PS73AF)	
WATER (UNII: 059QF0K00R)	
D&C RED NO. 22 (UNII: 1678RXX8RT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10095-005-01	30 g in 1 PACKAGE; 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	part333A	05/05/2015	

Labeler - World Perfumes, Inc (101312044)

Establishment

Name	Address	ID/FEI	Business Operations
World Perfumes, Inc		10 1312044	manufacture(10095-005)

Revised: 5/2015

World Perfumes, Inc