EL VALLE MERTHIOLATE- benzalkonium chloride liquid Pharmadel 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.

El Valle Merthiolate (Benz Chloride 0.13%)

Drug Facts

Drug facts

Active Ingredient & Purpose

Active ingredient	Purpose	
Benzalkonium chloride 0.13%	First aid antiseptic	

Uses

First aid to help prevent infection in

- minor cuts
- scrapes
- burns

Warnings

FOR EXTERNAL USE ONLY.

Do not use

- longer than 1 week, unless directed by a doctor
- in the eyes
- over large areas of the body

Ask a doctor before use if you have

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

Stop use and consult a doctor if

• conditions persist or gets worse

Keep out of reach of children.

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

Directions

- clean the affected area
- apply a small amount directly to the affected area 1 to 3 times a day
- may cover area with a sterile bandage

Other information

• do not use if clear seal over cap is missing or broken

Inactive ingredients

alcohol, FD&C red #40, water

Prinicpal Display Panel



EL VALLE MERTHIOLATE

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-375
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name Basis of Strength			
	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL	

Inactive Ingredients			
Ingredient Name Stre			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
ALCOHOL (UNII: 3K9958V90M)			
WATER (UNII: 059QF0KO0R)			

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758- 375-01	15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2023	05/31/2023
2	NDC:55758- 375-02	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/31/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/31/2023	

Labeler - Pharmadel LLC (030129680)

Revised: 6/2023 Pharmadel LLC