BITE AND STING RELIEF- benzocaine - 5.00% cream Top care

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 ingredients Purpose
Benzocaine 5.00%

Uses

For temporarily relief of pain and itching associated with insect bites

Warning

For external use only

When using this product avoid contact with eyes and mucous membranes

Stop use and ask a doctor if condition worsens• symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of the children

If product is swallowed, get medical help or contact a Poison Control Center right away In case of accidental ingestion, seek professional or contact a Poison Control Center immediately.

Direction

Adults and children 2 years of age and older: • apply to the affected area nor mre than 3 to 4 times daily. Children under 2 years of age: consult a doctor

Inactive ingredients

Water

PEG-2 Stearate

PEG-2 Stearate SE

SD Alcohol 40

Polyethylene

Hydrocortisone

Methylparaben

Aloe Barbadensis Leaf Extract

Propylparaben

Chamomilla Recutita (Matricaria) Flower Extract

Propylene Glycol

Diazolidinyl Urea

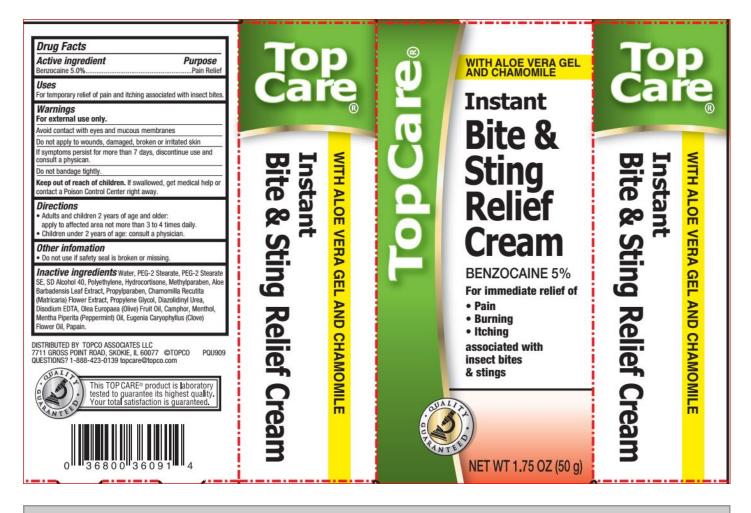
Disodium EDTA

Olea Europaea (Olive) Fruit Oil

Camphor

Menthol

Mentha Piperita (Peppermint) Oil



BITE AND STING RELIEF

benzocaine - 5.00% cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-718
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Benzocaine (UNII: U3RS Y48 JW5) (BENZOCAINE - UNII: U3RS Y48 JW5)	Benzocaine	5 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
PEG-2 Stearate (UNII: 94YQ11Y95F)		
ALCOHOL (UNII: 3K9958V90M)		
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)		
Hydrocortisone (UNII: WI4X0X7BPJ)		

Methylparaben (UNII: A2I8C7HI9T)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
Propylparaben (UNII: Z8IX2SC1OH)		
CHAMO MILE (UNII: FGL3685T2X)		
Propylene Glycol (UNII: 6DC9Q167V3)		
Diazolidinyl Urea (UNII: H5RIZ3MPW4)		
EDETATE DISO DIUM (UNII: 7FLD91C86K)		
OLIVE OIL (UNII: 6UYK2W1W1E)		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)		
Menthol (UNII: L7T10EIP3A)		
Peppermint (UNII: V95R5KMY2B)		
CLOVE OIL (UNII: 578389 D6 D0)		
Papain (UNII: A236A06Y32)		

I	Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:36800-718-02	1 in 1 CARTON	08/06/2012		
1		50 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	08/06/2012	

Labeler - Top care (006935977)

Registrant - Product Quest Mfg. (927768135)

Establishment				
Name	Address	ID/FEI	Business Operations	
Product Quest Mfg.		927768135	manufacture(36800-718), label(36800-718)	

Revised: 7/2018 Top care