

**INSECT BITE RELIEF 01- menthol spray**  
**Cosmuses Cosmetics (Ningbo) Co., Ltd.**

*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.*

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**insect bites relief spray**

**Drug Facts**

**Active Ingredients**

Menthol 1%

**Purpose**

Anti-itch

Insect bite relief spray

**Uses**

Temporarily relieves itching associated with minor skin irritations, inflammation and rashes due to: eczema, psoriasis, insect bites, detergents, jewelry, cosmetics, soaps, seborrheic dermatitis and more.

**Warnings**

For external use only.

**Do not use**

- in or near the eyes
- for diaper rash; ask a doctor

Ask a doctor before use if you are using any other hydrocortisone product.

Stop use and ask a doctor if

- condition worsens or if symptoms persist for more than 7 days
- symptoms last 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.

**Directions**

- Apply to affected area not more than 3 to 4 times daily.

- Children under 2 years, do not use; ask a doctor.

## Other information

Protect from excessive heat (40 °C/ 104 °F)

## Inactive ingredients

Alcohol, Aqua, Menthyl Lactate, Borneol, Butylene Glycol, Glycerin

Do not begin use of any hydrocortisone product unless you've asked a doctor. Do not use in the genital area if you have a vaginal discharge. Consult a doctor. Do not use more than directed unless told to do so by a doctor.

# Insect Bite Relief Spray

<b>Drug Facts</b>	<b>Active ingredient</b> Menthol 1%.....	<b>Purpose</b> Anti-itch	<b>Insect Bite Relief Spray</b>	<b>Keep out of reach of children.</b> If swallowed, get medical help or call a Poison Control Center right away.
	<b>Uses:</b> Temporarily relieves itching associated with minor skin irritations, inflammation and rashes due to: eczema, psoriasis, insect bites, detergents, jewelry, cosmetics, soaps, seborrheic dermatitis and more.			<b>Directions:</b> • Apply to affected area not more than 3 to 4 times daily. • Children under 2 years, do not use; ask a doctor.
	<b>Warnings:</b> For external use only.			<b>Other information:</b> Protect from Excessive Heat (40°C/104°F).
	<b>Do not use</b> • in or near the eyes • for diaper rash; ask a doctor.			<b>Inactive ingredients:</b> Alcohol, Aqua, Menthyl Lactate, Borneol, Butylene Glycol, Glycerin.
	<b>Ask a doctor before use if you are</b> using any other hydrocortisone product.			Do not begin use of any hydrocortisone product unless you've asked a doctor. Do not use in the genital area if you have a vaginal discharge. Consult a doctor. Do not use more than directed unless told to do so by a doctor.
	<b>Stop use and ask a doctor if</b> • condition worsens or if symptoms persist for more than 7 days • symptoms last more than 7 days or clear up and occur again within a few days.			Distributed by: Bulletline LLC, Miami, FL33013 • 1-800-794-3620 NDC-51414-106-02 ASI#42424 MADE IN CHINA 10ml/0.35fl. oz Exp: 06/2026 PO# M000033443

## INSECT BITE RELIEF 01

menthol spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82953-011
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>MENTHYL LACTATE, (-)-</b> (UNII: 2BF9E65L7I)	
<b>BORNEOL</b> (UNII: M89NIB437X)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82953-011-03	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2022	
2	NDC:82953-011-02	20 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2022	
3	NDC:82953-011-01	10 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	09/30/2022	

**Labeler** - Cosmuses Cosmetics (Ningbo) Co., Ltd. (725290934)

**Registrant** - Cosmuses Cosmetics (Ningbo) Co., Ltd. (725290934)

### Establishment

Name	Address	ID/FEI	Business Operations
Cosmuses Cosmetics (Ningbo) Co., Ltd.		725290934	manufacture(82953-011)

Revised: 7/2023

Cosmuses Cosmetics (Ningbo) Co., Ltd.