MYDERM BITE RELIEF- benzocaine ointment Inspec Solutions 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.

MyDerm Bite Relief Mediocated Ointment

Active Ingredient:

Benzocaine - 5.0%

Benzocaine - 10.0%Pain Relief

Temporary relief of pain and itching associated with insect bites

For external use only

When using this product • avoid contact with the eye

Stop use and ask a doctor if • condition worsens, or if 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.

Direction Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.

Children under 2 years of age: consult a physician

Aloe Barbadensis Leaf Extract

Camphor

Chamomilla Recutita (Matricaria) Flower Extract

Diazolidinyl Urea

Disodium EDTA

Eugenia Caryophyllus (Clove) Flower Oil

Hydrocortisone

Inactive Ingredients:

Mentha Piperita (Peppermint) Oil

Menthol

Methylparaben

Olea Europaea (Olive) Fruit Oil

Papain

PEG-2 Stearate

PEG-2 Stearate SE

Polyethylene

Propylene Glycol

Propylparaben

SD Alcohol 40

Water



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Shake well before use.

Active ingredient Benzocaine 5.0% Uses For the temporary relief of pain and itching associated with insect titles. **Drug Facts**

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symptoms persist for more
than 7 days or clear up and occur again within a few days.

Pregnant or breast-feeding, ask a health professional before use. Keep out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions • Adults and children 2 years of age and older; apply to affected area not more than 3 to 4 times daily. • Children under 2 years of age; consult a

broken or missing. Other information . Do not use if safety seal is

Inactive ingredients Aoe Barbadensis Leaf Extract, Camphor, Chamomila Reculta (Matricaria) Hower Extract, Dazdidiny (Irus, Dasdium EDIA, Espania Carpothyllus (Clove) Hower Oil, Hydrocordsone, Mentha Pipella (Peppermint) Oil, Mentha (Methylparathen, Olae Europaea (Olive) Fout Oil, Paparin, PEG-2 Stearate, PEG-2 Stearate SE, Polyethylene, Propylene Glycol, Propylparathen, SD Ajcothol 40, Water,



Questions?1-855-693-3761

benzocaine ointment

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72667-019

Route of Administration TOPICAL

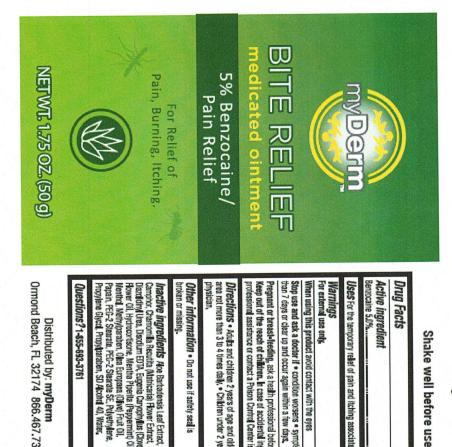
Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|--------------|
| BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5) | BENZOCAINE | 5 g in 100 g |

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| PEG-8 DIMETHICONE (UNII: GIA7T764OD) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| WATER (UNII: 059QF0KO0R) | |
| PEG-2 STEARATE (UNII: 94YQ11Y95F) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| CAMPHOR (NATURAL) (UNII: N20HL7Q941) | |
| MATRICARIA CHAMOMILLA FLOWERING TOP OIL (UNII: SA8AR2W4ER) | |
| CLOVE OIL (UNII: 578389D6D0) | |
| PROPYLENE GLYCOL 1,2-DISTEARATE (UNII: T65PN3O37H) | |
| OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT) | |
| ALOE (UNII: V5VD430YW9) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| DIAZOLIDINYL UREA (UNII: H5RIZ 3MPW4) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| MEDIUM DENSITY POLYETHYLENE (UNII: 3W404QE89S) | |
| MENTHOL (UNII: L7T10EIP3A) | |
| HYDROCORTISONE (UNII: W4X0X7BPJ) | |

| Product Characteristics | |
|--------------------------------|--------------|
| Color | Score |
| Shape | Size |
| Flavor | Imprint Code |
| Contains | |

| | Packaging | | | | |
|---|-----------|----------------------|---|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | | NDC:72667-019- 01 | 50 g in 1 TUBE; Type 0: Not a Combination Product | 12/14/2021 | |
| П | | | | | |





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Active ingredient
Benzocaine 5.0%

Purpose Pain Relief

ISES For the temporary relief of pain and itching associated with insect bites.

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Hower Oli, Hydrocortsone, Mentha Piperlia (Pappermint) Oli, Menthal, Methylparaben, Olea Europaea (Olive) Fruit Oli, Papan, PEG-2 Stearate, PEG-2 Stearate SE, Polyethylene, uestions?1-855-693-3761 ene Glycol, Propylparatien, SD Alcohol 40, Water.

Diazolidinyi Urea, Disodium EDTA, Eugenia Caryophyllus (Clove

Distributed by: myDerm Ormond Beach, FL 32174 866.467.7320

Marketing Information

Marketing

Application Number or Monograph

Marketing Start Marketing End

| OTC monograph not final part348 | 12/14/2021 | |
|---------------------------------|------------|--|

Labeler - Inspec Solutions LLC. (081030372)

| Establishment | | | | |
|-----------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Inspec Solutions LLC. | | 081030372 | manufacture(72667-019) | |

Revised: 1/2023 Inspec Solutions LLC.