# MONISTAT CARE INSTANT ITCH RELIEF- benzocaine spray Insight Pharmaceuticals 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.

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## **Monistat Care Itch Relief Spray**

Monistat Care – Benzocaine 20% / Topical analgesic

**PDP** 

**Monistat Care** 

20 % Benzocaine / Topical analgesic

**Instant Itch Relief Spray** 

**NET WT. 2 OZ (57 g)** 

**Drug Facts** 

### **Active ingredient**

Benzocaine 20%

## **Purpose**

Topical analgesic

#### Uses

Temporary relief of pain and itching

## Warnings

#### For external use only

**Allergy alert:** do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

**Contents under pressure.** Do not puncture or incinerate. Flammable mixture; do not use near fire or flame, or expose to heat or temperatures above 49°C (120°F). Use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.

## When using this product

avoid contact with the eyes

#### Stop use and ask a doctor if

- condition worsens, or symptoms persists for more than 7 days
- symptoms 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 (1-800-222-1222) right away.

#### **Directions**

- **shake can well,** hold 8" to 12" from affected area; spray liberally.
- **adults and children 12 years and older:** apply to affected area not more than 3 to 4 times daily
- **children under 12 years:** consult a physician

## Other information

Store at room temperature  $15^{\circ}-25^{\circ}\text{C}$  ( $59^{\circ}-77^{\circ}\text{F}$ ).

## **Inactive ingredients**

Polyethylene glycol 300

**Propellant:** Isobutane, normal butane, propane

## Questions?

Call toll free 1-877-666-4782

#### PRINCIPAL DISPLAY PANEL

MONISTAT
Care
20% Benzocaine/ Tropical Analgesic
MAXIMUM STRENGTH
INSTANT
Itch Relief
SPRAY
Net WT.2 OZ(57g)



#### MONISTAT CARE INSTANT ITCH RELIEF

benzocaine spray

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63736-050

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength | Strength       |
|---|-------------------|----------------|
| BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII: U3RS Y48 JW5) | BENZOCAINE        | 11.4 g in 57 g |

| Inactive Ingredients                         |          |
|--|----------|
| Ingredient Name                              | Strength |
| POLYETHYLENE GLYCOL 300 (UNII: 5655G9 Y8 AO) |          |

| ı | Packaging          |  |                      |                    |  |  |
|---|--------------------|--|----------------------|--------------------|--|--|
| l | # Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |  |  |
| l | 1 NDC:63736-050-01 | 57 g in 1 CAN; Type 0: Not a Combination Product | 10 /0 1/20 17        |                    |  |  |

| Marketing Information   |  |                      |                    |  |  |
|-------------------------|--|----------------------|--------------------|--|--|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |  |
| OTC MONOGRAPH NOT FINAL | part348                                  | 10 / 0 1 / 20 17     |                    |  |  |
|                         |  |                      |                    |  |  |

## Labeler - Insight Pharmaceuticals LLC (055665422)

Revised: 12/2017 Insight Pharmaceuticals LLC