**BENZOCAINE AND RESORCINOL - benzocaine and resorcinol cream**
**Pharma Pac, 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.*

---

**drug facts**

| **Active ingredients** | **Purpose** |
|---|---|
| Benzocaine 20% | External Analgesic |
| Resorcinol 3% | External Analgesic |

**Use temporarily relieves itching**

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Use** temporarily relieves itching

**Other information** - store at 20 degrees - 25 degrees C (68 degrees - 77 degrees F)

**Warnings**

**For external use only.**

**When using this product** avoid contact with the eyes

**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

**Do not apply** over large areas of the body

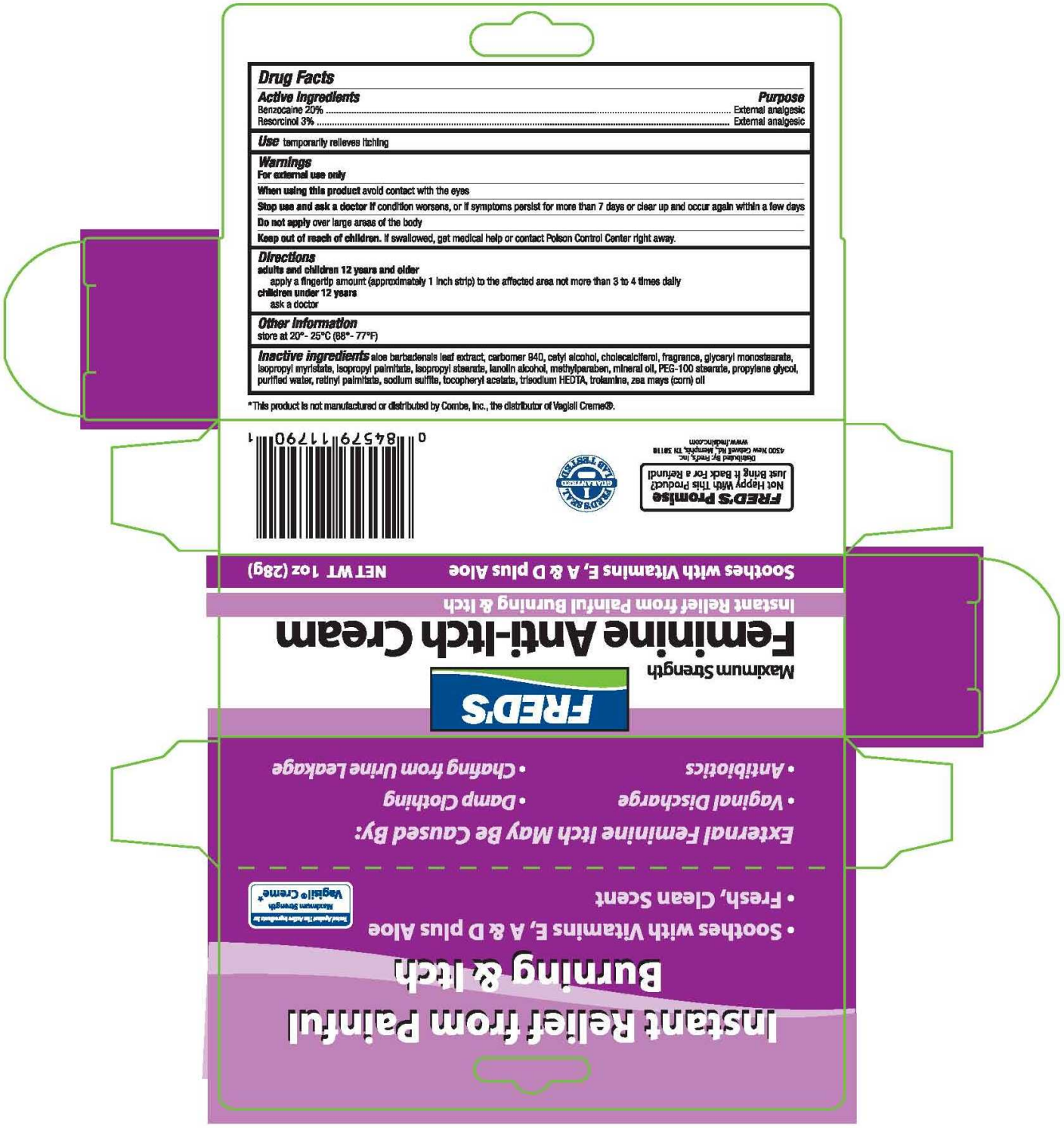
**Directions**

**adults and children 12 years and older**
apply a fingertip amount (approximately 1 inch strip) to the affected area not more than 3 to 4 times daily

**children under 12 years**
ask a doctor

**Inactive Ingredients** aloe barbadensis leaf extract, carbomer 940, cetyl alcohol, cholecalciferol, fragrance, glyceryl monostearate,
isopropyl myristate, isopropyl palmitate, isopropyl stearate, lanolin alcohol, methylparaben, mineral oil, PEG-100 stearate, propylene glycol,
purified water, retinyl palmitate, sodium sulfite, tocopheryl acetate, trisodium HEDTA, trolamine, zea

mays (corn) oil




## BENZOCAINE AND RESORCINOL

benzocaine and resorcinol cream

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:67868-117 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **BENZOCAINE** (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5) | BENZOCAINE | 200 mg in 1 g |
| **RESORCINOL** (UNII: YUL4LO94HK) (RESORCINOL - UNII:YUL4LO94HK) | RESORCINOL | 20 mg in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **WATER** (UNII: 059QF0KO0R) | |
| **CARBOMER HOMOPOLYMER TYPE C** (UNII: 4Q93RCW27E) | |
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4) | |
| **ISOPROPYL PALMITATE** (UNII: 8CRQ2TH63M) | |
| **ISOPROPYL MYRISTATE** (UNII: 0RE8K4LNJS) | |
| **ISOPROPYL STEARATE** (UNII: 43253ZW1MZ) | |
| **LANOLIN ALCOHOLS** (UNII: 884C3FA9HE) | |
| **MINERAL OIL** (UNII: T5L8T28FGP) | |
| **POLYOXYL 100 STEARATE** (UNII: YD01N1999R) | |
| **VITAMIN A** (UNII: 81G40H8B0T) | |
| **VITAMIN D** (UNII: 9VU1KI44GP) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **SODIUM SULFITE** (UNII: VTK01UQK3G) | |
| **ALPHA-TOCOPHEROL** (UNII: H4N855PNZ1) | |
| **TRISODIUM HEDTA** (UNII: K3E0U7O8KI) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **CORN OIL** (UNII: 8470G57WFM) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:67868-117-90 | 28 g in 1 TUBE | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part348 | 05/19/2009 | |

## Labeler - Pharma Pac, LLC (140807475)

## Registrant - Pharma Pac, LLC (140807475)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Pharma Pac, LLC | | 140807475 | manufacture |