

BENZOCAINE AND RESORCINOL - benzocaine and resorcinol ointment

RiteAid

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 ingredient | Purpose |
|--------------------------|--------------------|
| Benzocaine 20%..... | External analgesic |
| Resorcinol 3%..... | External analgesic |

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Use temporarily relieves itching

Keep out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

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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

keep out of teh reach of children.If swallowed get medical help or contact a Poison Control Center right away

Directions

- **adults and children 12 years and older**

apply a fingertip amount (approximately 1 inch strip) to the affected area not more than 3 or 4 times daily.

- **children under 12 years**

ask a doctor

Other information

Store at 20 degrees to 25 degrees C (68 degrees to 77 degrees F)

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, zeamays (corn) oil



BENZOCAINE AND RESORCINOL

benzocaine and resorcinol ointment

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11822-2890 |
| 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: A218C7HI9T) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:11822-2890-2 | 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 - RiteAid (014578892)

Registrant - Pharma Pac, LLC (140807475)

Establishment

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