GOOD NEIGHBOR PAIN RELIEF- benzocaine liquid AmerisourceBergen Drug Corporation (Good Neighbor Pharmacy)

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

Benzocaine, 20%

Purpose

Oral anesthetic

Uses

Provides temporary relief of pain associated with the following mouth and gum irritations:

- toothache
- sore gums
- canker sores
- braces
- minor dental procedures
- dentures

□ Warnings

□**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.

When using this product

- avoid contact with eyes
- do not exceed recommended dosage
- do not use for more than 7 days unless directed by a doctor or dentist

Stop use and ask a doctor or dentist if

- sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens
- swelling, rash, or fever develops

Example 2 IKeep out of reach of children

• If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away

Directions

- **Adults and children 2 years of age and older:**
- wipe liquid on with cotton, or cotton swab, or finger tip.
- apply to the affected area up to 4 times daily of as directed by a doctor or dentist.

- **Children under 12 years of age:** adult supervision should be given in the use of this product.
- **Children under 2 years of age:** consult a doctor or dentist.

Inactive ingredients

Benzyl alcohol, FD&C Blue #1, FD&C Red #40, D&C yellow #10, Flavor, Methylparaben, Polyethylene Glycol, Propylene Glycol, Saccharin

7.6X3.8CM



Manufacturer: Lee Pharmaceuticals



293C 40% 293C

7.6x14.9cm





Do not use if plastic blister or backing material is broken or seperated

Drug Facts

Active ingredient

Purpose Oral and

Uses Provides temporary relief of pain associated with the following mouth and gum irritations: • toothache • sore gums • canker sores • braces • minor dental procedures • dentures

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Keep out of the reach of children. If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions
• Adult and children 2 years of age and older:

- wipe liquid on with cotton, or cotton swab, or fingertip
 apply to the affected area up to 4 times daily or as directed by a doctor or
- Children under 12 years of age: adult supervision should be given in the use
- Children under 2 years of age: consult a doctor or dentist

Other information

Store at room temperature

Inactive ingredients

benzyl alcohol, FD&C Blue #1, FD&C Red #40, FD&C Yellow #10, flavor, methylparaben, polyethylene glycol, propylene glycol, saccharin

*This product is not manufactured or distributed by Wyeth Consumer Healthcare, owner of the registered trademark Anbesol

Distributed By AmerisourceBergen 1300 Morris Drive Chesterbrook, PA 19087 Visit us at

www.goodneighborpharmacy.com Questions or comments:

800-950-5337 Cat. No. 0386-000 180386A, Rev. 3/12



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293C 40% 2930

GOOD NEIGHBOR PAIN RELIEF

benzocaine liquid

Product Information

HUMAN OTC DRUG Item Code (Source) NDC:46122-030 Product Type

ORAL

Active Ingredient/Active Moiety

| 9 | <u> </u> | | |
|------------------|--|-------------------|----------------|
| | Ingredient Name | Basis of Strength | Strength |
| BENZO CAINE (UNI | I: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5 | BENZOCAINE | 200 mg in 1 mL |

| Inactive Ingredients | | | | |
|--|----------|--|--|--|
| Ingredient Name | Strength | | | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | | | | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | | | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | | | | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | | | | |
| METHYLPARABEN (UNII: A2I8 C7HI9 T) | | | | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | | |
| SACCHARIN (UNII: FST467XS7D) | | | | |

| F | Packaging | | | | |
|---|------------------|--------------------------|----------------------|--------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:46122-030-05 | 1 in 1 BLISTER PACK | | | |
| 1 | NDC:46122-030-06 | 15 mL in 1 BOTTLE, GLASS | | | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part356 | 08/01/2008 | | |
| | | | | |

Labeler - AmerisourceBergen Drug Corporation (Good Neighbor Pharmacy) (007914906)

Registrant - Lee Pharmaceuticals (056425432)

| Establishment | | | | |
|------------------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| AmerisourceBergen Drug Corporation | | 007914906 | label(46122-030) | |

| Establishment | | | |
|---------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| Lee Pharmaceuticals | | 056425432 | pack(46122-030) |

| Establishment | | | | | |
|---------------|---------|-----------|------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| Unipack | | 009248480 | manufacture(46122-030) | | |

| Establishment | | | | |
|------------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Samson Pharmaceuticals | | 088169581 | manufacture(46122-030) | |

Revised: 6/2013

AmerisourceBergen Drug Corporation (Good Neighbor Pharmacy)