

**LITTLE COLDS SORE THROAT RELIEF MELT AWAYS- benzocaine granule
Medtech Products Inc.**

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.

Little Colds Sore Throat Relief Melt Aways

Brand: Little Remedies

Product Name: Little Colds Sore Throat Melt Aways

Size: 12 packets

Country: USA

Artwork Description: IFC

Artwork #: LC14101

Active ingredients

Benzocaine 6 mg (*in each packet*)

Purpose

Oral Anesthetic/Analgesic

Use

For the temporary relief of occasional minor irritation, pain, sore throat, and sore mouth.

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.

Sore Throat Warning: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a doctor promptly. Do not use more than 2 days or administer to children under (3) years of age unless directed by a doctor.

When using this product:

do not exceed recommended dosage.

Stop use and ask a dentist or doctor if:

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

If pregnant or breast-feeding

ask a health care professional before use.

Keep out of reach of children.

In case of overdose or accidental poisoning, get medical help or contact a Poison Control Center right away.

Directions

- Empty entire contents of packet onto tongue, allow to dissolve, then swallow
- For best taste, do not chew granules

| Age | Dose |
|--------------------|---------------------------------------|
| under 3 years | Consult a doctor |
| 3 to under 6 years | 1 packet every 2 hours as needed |
| 6 years and over | 1 – 2 packets every 2 hours as needed |

Other Information

- Store at 59–77°F (15–25°C).
- **Tamper Evident:** Do not use if foil packets are broken.
- Check expiration date before using.

Inactive Ingredients

cocoa butter, crospovidone, flavor, glucose, hypromellose, polyethylene glycol, polysorbate 80, sodium lauryl sulfate, sucralose, sucrose, talc

Questions

For further information you may contact us at: **1-800-7-LITTLE**, or visit us at www.LittleRemedies.com.

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Irvington, NY 10533

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LC14101

PRINCIPAL DISPLAY PANEL

MEDICATED FOR KIDS 3+

LITTLE

Colds®

By Little

Remedies

NEW!

SORE

THROAT

RELIEF

Melt Aways

Benzocaine – Oral Anesthetic / Analgesic

- **Relives Pain**
- **Soothes Throat**

- No measuring, no mixing, no worries – just relief!

Great tasting

GRAPE flavor

12 - 6 mg Benzocaine granule packets



LITTLE COLDS SORE THROAT RELIEF MELT AWAYS

benzocaine granule

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63029-102 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5) | BENZOCAINE | 6 mg |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|--|
| Color | WHITE | Score | |
| Shape | | Size | |
| Flavor | GRAPE | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|----------------------------|-----------------------------|---------------------------|
| 1 | NDC:63029-102-12 | 12 in 1 CARTON | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC MONOGRAPH FINAL | part356 | 12/31/2009 | |

Labeler - Medtech Products Inc. (122715688)

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Medtech Products Inc.