

**TRIAL ANTACID - calcium carbonate tablet**  
**Zee Medical 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.*

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**Drug Facts**

Active Ingredient (in each tablet) Calcium Carbonate-420 mg

Purpose-Antacid

Uses relieves:

- heartburn
- acid indigestion
- sour stomach
- upset stomach due to these symptoms

Directions

- chew 2 to 4 tablets. Repeat hourly if symptoms return.
- do not take more than 18 tablets in 24 hours
- do not use the maximum dosage more than 2 weeks

Warnings

Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids may interfere with certain prescription drugs

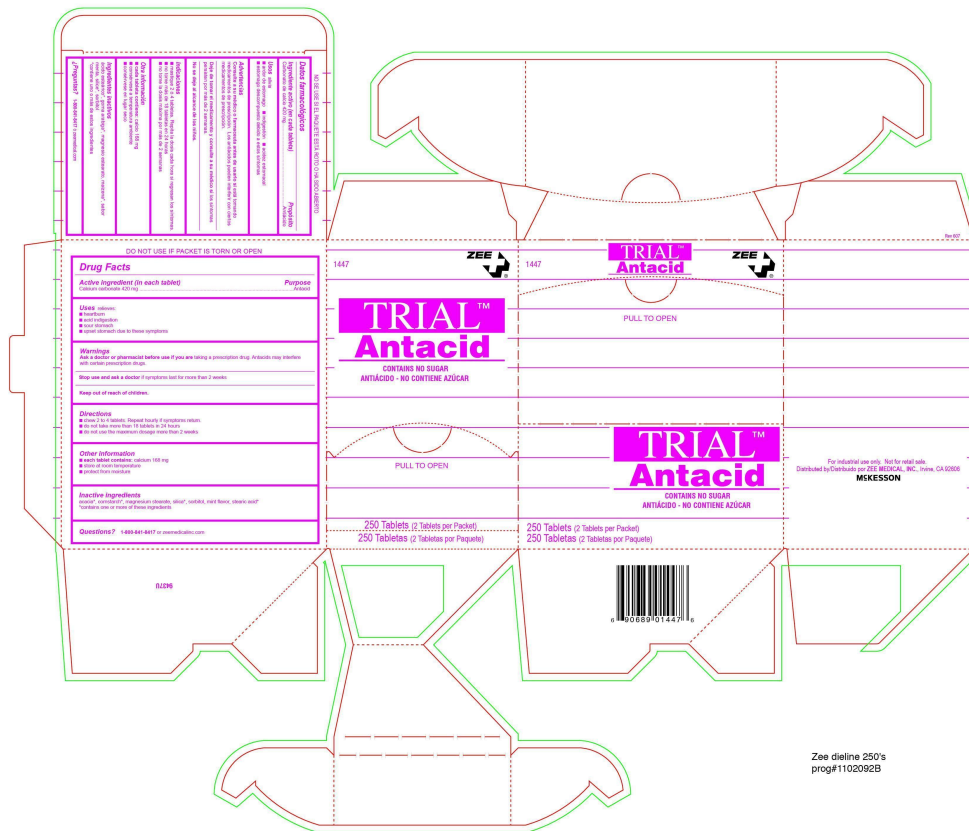
If pregnant or breast-feeding baby, ask a health professional before use

**KEEP OUT OF REACH OF CHILDREN.** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

inactive ingredients

acacia\*, cornstarch\*, magnesium stearate, silica\*, sorbitol, mint flavor, stearic acid\* \*contains one or more of these ingredients

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## TRIAL ANTACID

calcium carbonate tablet

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:35418-310 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength |
|--|-------------------|----------|
| CALCIUM CARBONATE (UNII: H0G9379FGK) (CARBONATE ION - UNII:7UJQ50PE7D) | CALCIUM CARBONATE | 420 mg   |

### Inactive Ingredients

| Ingredient Name                       | Strength |
|---------------------------------------|----------|
| SORBITOL (UNII: 506T60A25R)           |          |
| ACACIA (UNII: 5C5403N26O)             |          |
| MAGNESIUM STEARATE (UNII: 70097M6I30) |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)    |          |
| STARCH, CORN (UNII: O8232NY3SJ)       |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)       |          |

## Product Characteristics

|                 |                       |                     |          |
|-----------------|-----------------------|---------------------|----------|
| <b>Color</b>    | white (snow white)    | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND (ZEE;TL)        | <b>Size</b>         | 13mm     |
| <b>Flavor</b>   | SPEARMINT (spearmint) | <b>Imprint Code</b> | ZEE;TL   |
| <b>Contains</b> |                       |                     |          |

## Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:35418-310-69 | 500 in 1 CARTON     |                      |                    |
| 1 | NDC:35418-310-68 | 50 in 1 CARTON      |                      |                    |
| 1 | NDC:35418-310-67 | 125 in 1 CARTON     |                      |                    |
| 1 | NDC:35418-310-02 | 2 in 1 PACKET       |                      |                    |

## Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part331                                  | 06/12/2012           |                    |

**Labeler** - Zee Medical Inc (009645623)

**Registrant** - Ultra Seal Corporation (085752004)

## Establishment

| Name                        | Address | ID/FEI    | Business Operations    |
|-----------------------------|---------|-----------|------------------------|
| Ultratab Laboratories, Inc. |         | 151051757 | manufacture(35418-310) |

## Establishment

| Name                   | Address | ID/FEI    | Business Operations |
|------------------------|---------|-----------|---------------------|
| Ultra Seal Corporation |         | 085752004 | repack(35418-310)   |

Revised: 11/2012

Zee Medical Inc