

ORAL-B ANTI-BACTERIAL- cetylpyridinium chloride liquid

Oral-B Laboratories

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.

Oral -B®

Anti-Bacterial Rinse

Drug Facts

Active ingredient

Cetylpyridinium Chloride 0.05%

Purpose

Anti-bacterial

Use

To fight plaque and bad breath bacteria.

Warnings

Keep out of the reach of children.

Not for use by children under six years of age.

Children over six should be supervised when using this product.

Do not use if shrinkband is broken or missing.

Do not swallow.

Directions

Rinse twice daily, after brushing, with 1/2 a capful (15 ml) for about 30 seconds.

Other information

Store above freezing.

Inactive ingredients

Water, Glycerin, Alcohol (9.3%), Flavor, Poloxamer 407, Methylparaben, Sodium Saccharin, Propylparaben, FD&C Blue #1, and D&C Yellow #10

Question or comments ?

1-800-56-ORALB

<http://www.oralb.com>

Distributed by:

Oral-B, A Division of
Procter & Gamble
Cincinnati, OH 45202

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Made in Colombia

PRINCIPAL DISPLAY PANEL - 500ml Label

Oral-B®

Anti-Bacterial Rinse

- Dual action formula kills plaque and bad breath bacteria on contact

NATURAL
MINT
FLAVOR

16.9 oz / 500ml



ORAL-B ANTI-BACTERIAL

cetylpyridinium chloride liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0041-1420 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| Cetylpyridinium Chloride (UNII: D9OM4SK49P) (Cetylpyridinium - UNII:CUB7JI0JV3) | Cetylpyridinium Chloride | 500 ug in 1 mL |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|--|
| Color | GREEN | Score | |
| Shape | | Size | |
| Flavor | MINT | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-----------------------------|-----------------------------|---------------------------|
| 1 | NDC:0041-1420-16 | 500 mL in 1 BOTTLE, PLASTIC | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final | part356 | 10/15/2005 | |

Labeler - Oral-B Laboratories (183102243)

Revised: 4/2010

Oral-B Laboratories