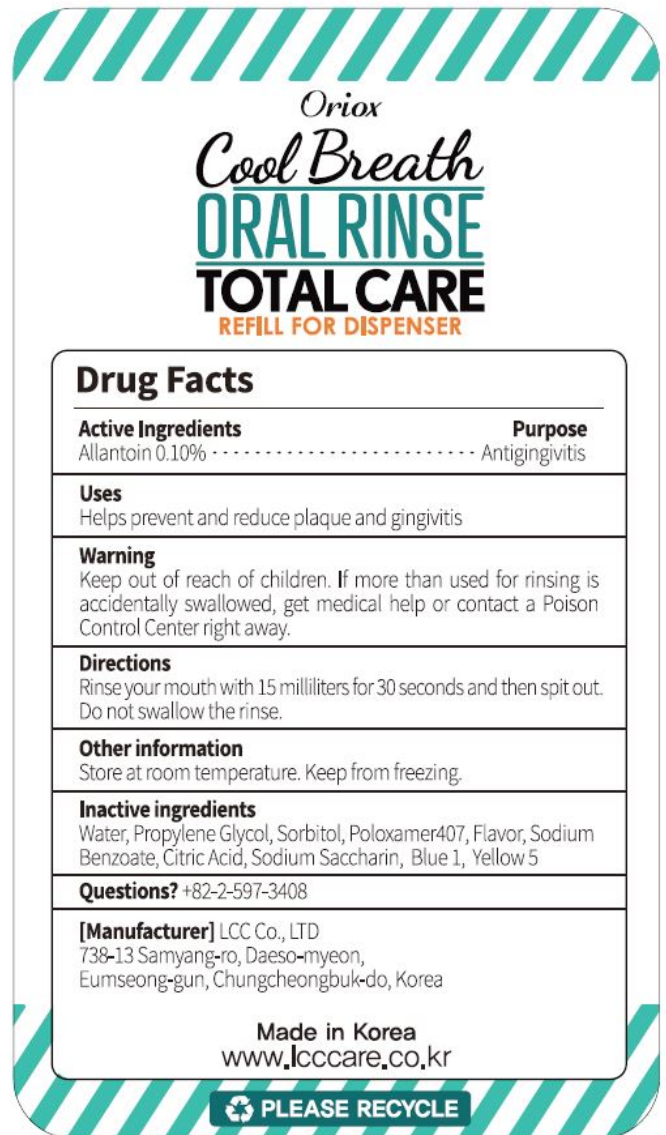


ORIOX COOL BREATH ORAL RINSE MILD- allantoin liquid
LCC LTD

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

allantoin

Package Label - Principal Display Panel



ORIOX COOL BREATH ORAL RINSE MILD

allantoin liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:77932-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z) | ALLANTOIN | 0.1 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SORBITOL (UNII: 506T60A25R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| POLOXAMER 407 (UNII: TUF21VW3M2) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:77932-002-01 | 1500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/31/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| unapproved drug other | | 03/31/2022 | |

Labeler - LCC LTD (688785286)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------|---------|-----------|------------------------|
| LCC LTD | | 688785286 | manufacture(77932-002) |

Revised: 3/2022

LCC LTD