

**LUTOOTH TOOTH WHITENING KIT- carbamide peroxide gel, dentifrice
Quorum Bio CO.,LTD**

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.

ACTIVE INGREDIENT

Carbamide Peroxide 15%

INACTIVE INGREDIENT

Water, etc.

PURPOSE

Tooth whitening

WARNINGS

Persons who CANNOT use Lutooth whitening kit.

- To be on the safe side, pregnant and breastfeeding women, children under the age of 14 should postpone tooth whitening.
- DO NOT use if teeth or gum are not healthy.
- Avoid ingestion and contact with eyes and skin. If contact occurs, wipe gel off and rinse with water.
- The LED device should not be used for other purpose.
- If sensitivity or gum irritation occurs, please stop using whitening gel and consult your dentist.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of babies and children.

INDICATIONS AND USAGE

Tooth Whitening Procedure & Method

You can find video clips of 'How to Use' at Lutooth homepage (<http://www.lutooth.com>)

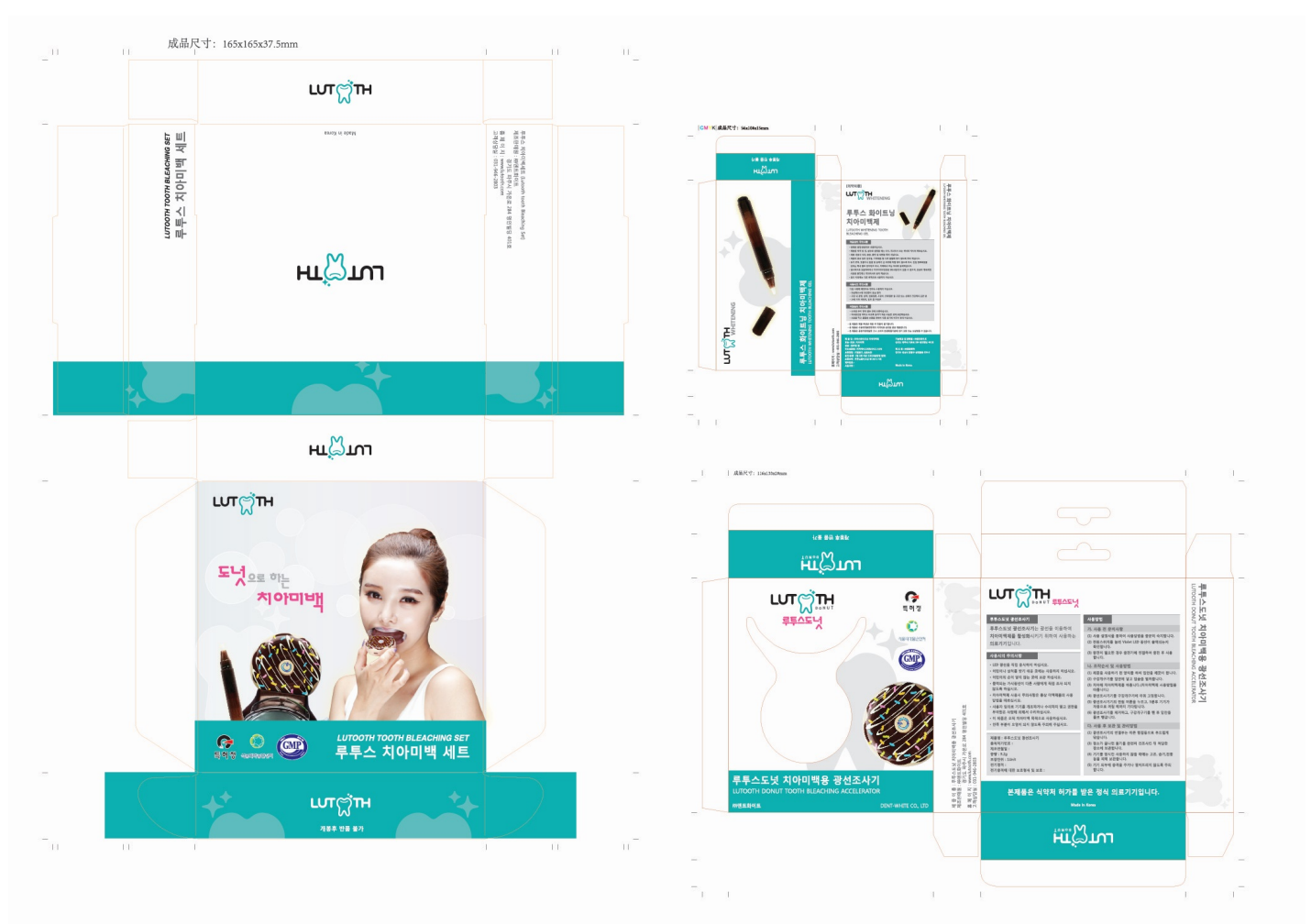
For detailed descriptions, please refer to the user manual inside the product package.

1. Exercise of installation
2. The Use of Whitening Stick
3. Put Cotton rolls
4. Put the lip&cheek retractor
5. Wipe saliva with the cotton roll
6. Apply whitening gels
7. Installation & Operation of LED Accelerator
8. Finishing 1 Cycle
9. Repeat (Three cycles a day)
10. Turn on LED light without whitening gels (Optional)

DOSAGE AND ADMINISTRATION

- If you want rapid effects, repeat 12 cycles (it takes one hour) or until desired whitening results are achieved.
- For the best effect, it is preferable to carry out every day for 4 days.
- Then, repeat the whitening cycle again for 4 days after 2 or 3 days break.

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL



LUTOOTH TOOTH WHITENING KIT

carbamide peroxide gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70635-0003
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	CARBAMIDE PEROXIDE	15 g in 100 mL

Inactive Ingredients

Ingredient Name		Strength		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70635-0003-2	4 in 1 PACKAGE	03/01/2016	03/01/2016
1	NDC:70635-0003-1	2 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:70635-0003-4	2 in 1 PACKAGE	01/01/2016	
2	NDC:70635-0003-3	2 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	01/01/2016		

Labeler - Quorum Bio CO.,LTD (695798936)

Registrant - Quorum Bio CO.,LTD (695798936)

Establishment

Name	Address	ID/FEI	Business Operations
Quorum Bio CO.,LTD		695798936	manufacture(70635-0003)

Revised: 10/2020

Quorum Bio CO.,LTD