

**PREMIUM WHITENING- hydrogen peroxide gel, dentifrice**  
**Hankuk Bowonbio Co., 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](#).*

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**Drug Facts**

active ingredient: hydrogen peroxide solution

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inactive ingredient: polyvinyl alcohol, povidone, sodium stannate, purified water

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for dental care use

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keep out of reach of the children

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apply Proper Amount of the gel on the teeth.

- For tooth only.
- Avoid contact with eyes.
- Do not swallow. If swallowed, get medical help.

dry the tooth to be applied



Tooth-whitening gel that delivers cleanness  
**Premium Whitening Gel**

- Approved by Korea Food and Drug Administration (No. Daejeon 148)
- Be in conformity with the requirements of the KGMP (ID No. 65613-895)
- Registered as an excellent venture business/ obtained the ISO9001 certification
- Won Gold Prize at 2006 Seoul International Invention Fair
- Won Bronze Medal at Korea Invention Patent Exhibition
- Awarded the ESH Value Management Prizes in 2006 and 2007 (by the administrator of the Public Procurement Service (PPS) and the Commissioner of the Korean Intellectual Property Office (KIPO))
- Selected as one of 100 Excellent Patented Products by the Hankuk Daily
- Chosen as an Excellent Business Brand by Seoul Metropolitan Government (the only company in the domestic toothpaste industry)

"A promise visible to the eyes - two applications a day will guarantee white teeth"

**1. Very simple**

an ergonomically engineered, penlike design will allow for a simple use whether at home, at work, when travelling, etc. anywhere any time.

**2. Easy and safe application**

unlike a grinding compound that abrades or peels the surface of a tooth, it forms an even layer of coating on the surface to exert an immediate effect on the tooth and thus keep it white without causing any damage to it.

**3. Approval from KFDA**

the gel made of tooth-whitening ingredients is a safe product, which is approved by Korea Food and Drug Administration.

- Product type : Tooth-whitening gel (A non-medical product, KGMP-complying manufacturer)
- Weight : 4.3ml
- Main ingredients : comprise peroxide etc
- Efficacy and effects : tooth whitening

Order of use

1.



Dry moisture from the teeth with a handkerchief or a piece of tissue

2.



Open the cap, tear off the lip, and then turn the dial clockwise. (Turn twice or three times clockwise) check with bare eyes whether there is an appropriate amount of gel squeezing out.

3.



When the gel starts coming out, turn the pen-like nibs on a tooth to apply evenly a half of one drop at a time after another

4.



Open the mouth lightly for no less than 30 seconds to 1 minute not to let the lips touch the teeth.

**PREMIUM WHITENING**

hydrogen peroxide gel, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60 319-100 1
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	35 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SODIUM STANNATE</b> (UNII: NJ7C1V83KG)	
<b>WATER</b> (UNII: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60319-1001-1	4.3 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2016	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/13/2011	

**Labeler** - Hankuk Bowonbio Co., Ltd (690045133)**Registrant** - Hankuk Bowonbio Co., Ltd (690045133)**Establishment**

Name	Address	ID/FEI	Business Operations
Hankuk Bowonbio Co., Ltd		690045133	manufacture(60319-1001)

Revised: 12/2019

Hankuk Bowonbio Co., Ltd