DR.WHITISS 15%- carbamide peroxide, sodium fluoride gel, dentifrice
NIBEC 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.

Drug Facts

Carbamide Peroxide 15%

Sodium Fluoride 0.25%

Povidone (K90), Anhydrous Ethanol, Hydroxyethyl Cellulose, Glycerin, Purified Water, Monobasic Potassium Phosphate, Sodium Hydroxide, L-Menthol, Potassium Nitrate

Whitening of discolored teeth

Keep gel out of reach of small children.

1. Gingival and general oral heath should be confirmed before treatment.
2. Brush your teeth before treatment.
3. Follow your dentist’s instructions on how to load gel into your custom whitening tray. Use no more than 1/3 to 1/2 of the syringe per tray.
4. Insert whitening tray in the mouth over the teeth. Seat the tray firmly agains the teeth. Remove excess gel with clean finger or soft toothbrush.(Rinse twice; do not swallow rinsed gel.)
5. Unless directed otherwise by your dentist, wear Dr.Whitiss 10% for 8-10 hours or overnight, Dr.Whitiss 15% for 4-6 hours, Dr.Whitiss20% for 2-4 hours, and Dr.Whitiss 35% for 30 minutes.
6. If significant sensitivity occurs, stop treatment and consult dentist.

1. Products containing peroxides are not recommended for children under the age of 18 and pregnant or lactating women.

2. Regular dental checkups and cleanings are important before and after bleaching to maintain a healthy smile.

3. Do not use this product if you are allergic to any of the ingredients.

4. If you have any questions regarding the appropriate use of this product, including how long it will take to bleach your teeth, please consult a dentist as soon as possible.

5. If irritation occurs such as redness, soreness, or swelling of the gums or mouth, discontinue use and consult a dental professional or physician.

6. Do not swallow. If a significant amount is swallowed, please call Poison Control immediately.

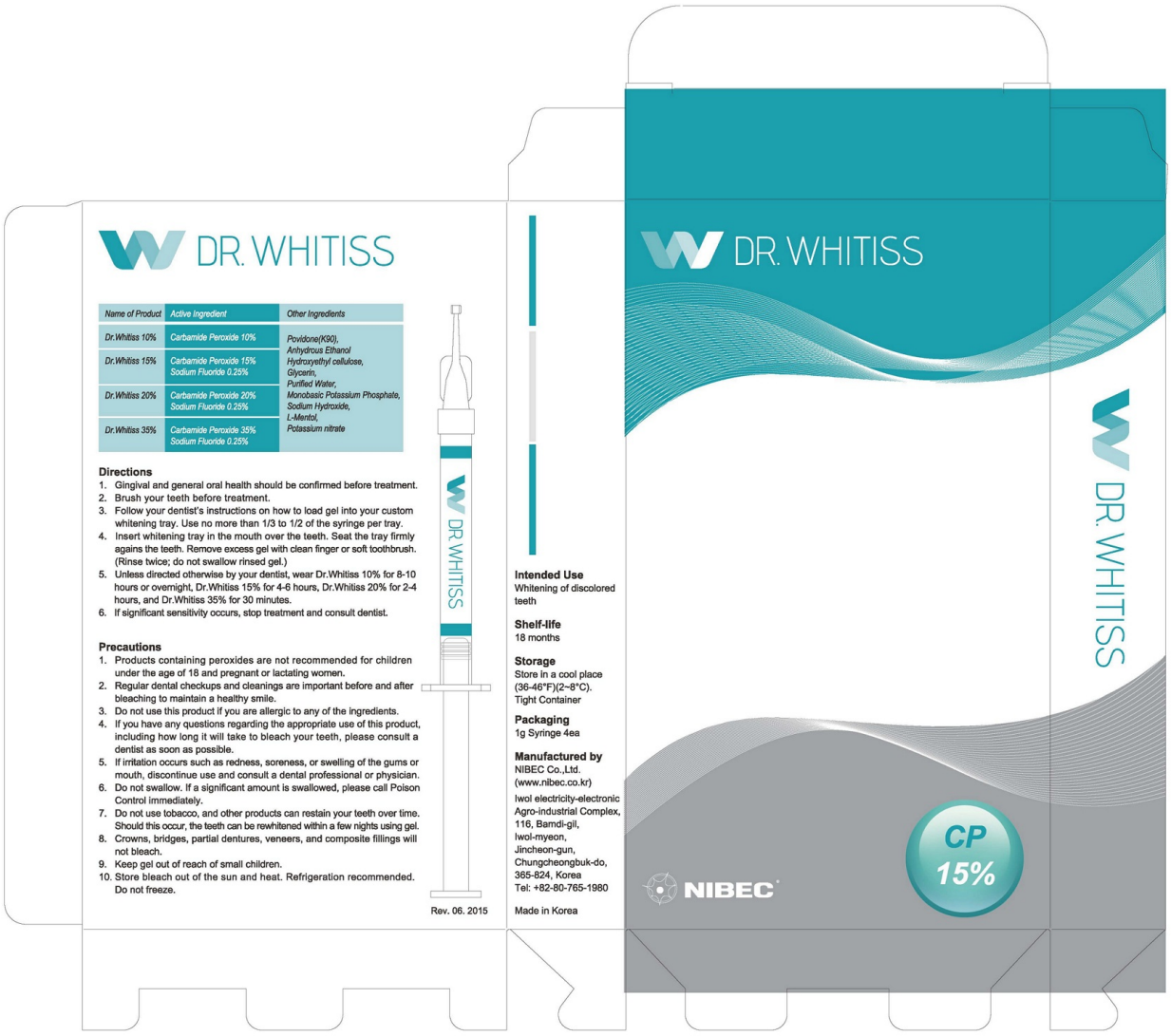
7. Do not use tobacco, and other products can restain your teeth over time. Should this occur, the teeth can be rewhitened within a few nights using gel.

8. Crowns, bridges, partial dentures, veneers, and composite fillings will not bleach.

9. Keep gel out of reach of small children.

10. Store bleach out of the sun and heat. Refrigeration recommended. Do not freeze.

for dental use only



DR.WHITISS 15%

carbamide peroxide, sodium fluoride gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47649-1401
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	CARBAMIDE PEROXIDE	150 mg in 1 g
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	2.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K90 (UNII: RDH86HJV5Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POTASSIUM NITRATE (UNII: RU45X2JN0Z)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47649-1401-2	4 in 1 PACKAGE	06/07/2015	
1	NDC:47649-1401-1	1 g in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/07/2015	

Labeler - NIBEC Co., Ltd. (687796909)

Registrant - NIBEC Co., Ltd. (687796909)

Establishment

Name	Address	ID/FEI	Business Operations
Nibec Co., Ltd		687796909	manufacture(47649-1401) , label(47649-1401) , pack(47649-1401)

Revised: 1/2023 NIBEC Co., Ltd.