

DR. WHITISS (8.3%)- carbamide peroxide 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

polyvinyl pyrrolidone (k=90), glycerin, anhydrous ethyl alcohol, distilled water, potassium dihydrogen phosphate, sodium hydroxide, lemon oil, orange oil, xylitol, l-menthol, potassium nitrate, propolis ext

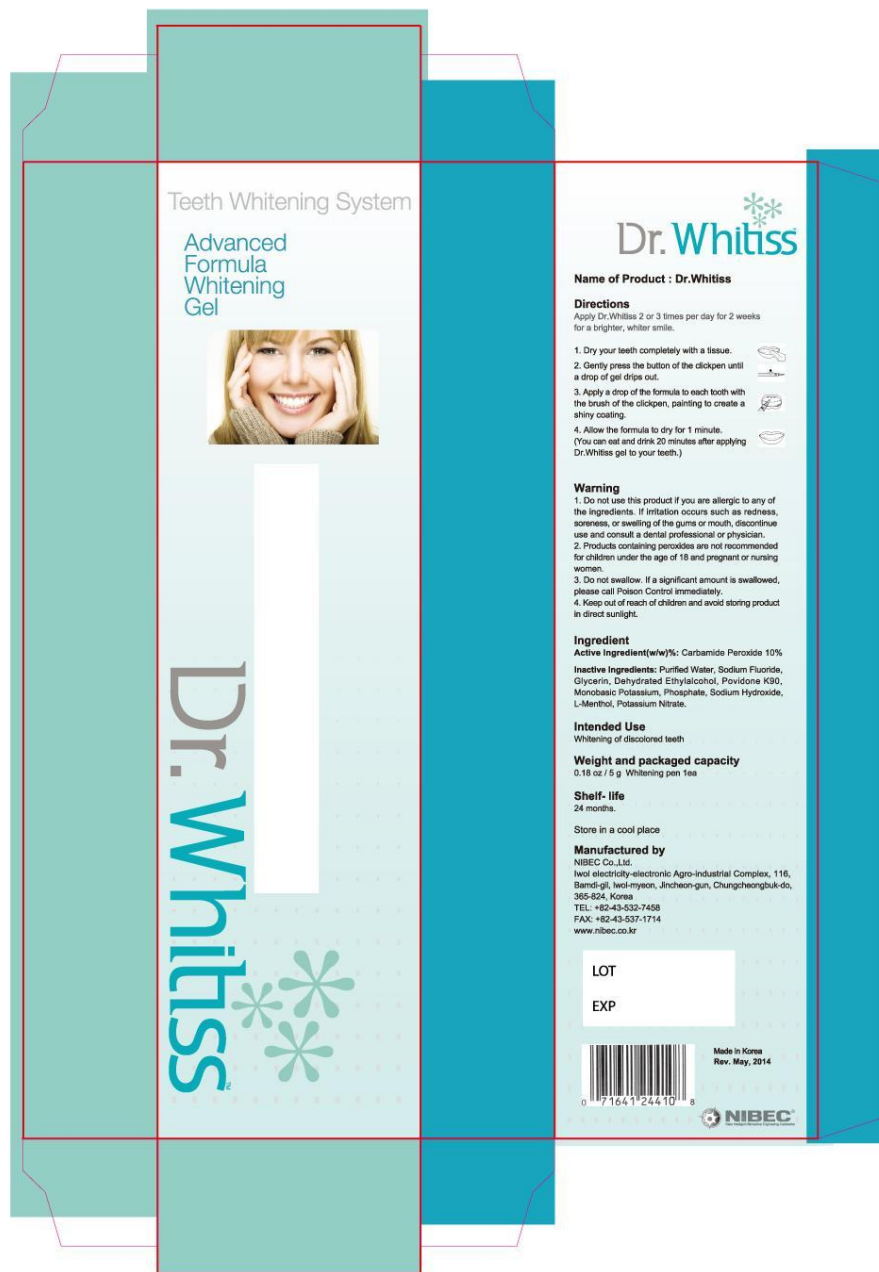
whitening of discolored vital teeth

keep out of reach of the children

apply 2 or 3 times per day for 2 weeks for a brighter, whiter smile

- 1) do not use on patient with sensitive to carbamide peroxide
- 2) do not use on patient with oral infection
- 3) no to be used by pregnant or lactating women or children under 18 years old
- 4) to be used under the supervision of a dentist
- 5) do not swallow this medication

for dental use only



DR. WHITISS (8.3%)

carbamide peroxide gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47649-9001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU8 1) (HYDROGEN PEROXIDE - UNII:BBX060AN9 V)	CARBAMIDE PEROXIDE	0.083 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K90 (UNII: RDH86HJV5Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
POTASSIUM NITRATE (UNII: RU45X2JN0Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47649-9001-3	4 in 1 PACKAGE	07/11/2014	
1	NDC:47649-9001-2	2 g in 1 CYLINDER; Type 0: Not a Combination Product		
2	NDC:47649-9001-1	5 g in 1 PACKAGE; Type 0: Not a Combination Product	07/11/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/11/2014	

Labeler - Nibec Co., Ltd (687796909)

Registrant - Nibec Co., Ltd (687796909)

Establishment

Name	Address	ID/FEI	Business Operations
Nibec Co., Ltd		687796909	manufacture(47649-9001)

Revised: 11/2017

Nibec Co., Ltd