DR.WHITISS 20%- 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

pyrrolidone (k=90), hydroxyethyl cellulose, glycerin, purified water, monobasic potassium phosphate, sodiu hydroxide, l-menthol, potassium nitrate, anhydrous ethanol

whitening of discolored teeth

keep out of reach of the 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) 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 20%

carbamide peroxide gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47649-1201
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	CARBAMIDE PEROXIDE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K90 (UNII: RDH86HJV5Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POTASSIUM NITRATE (UNII: RU45X2JN0Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47649-1201-2	4 in 1 PACKAGE	06/07/2015	
1	NDC:47649-1201-1	1 g in 1 SYRINGE; 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	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(47649-1201)

Revised: 12/2018 Nibec Co., Ltd