

DR.WHITISS 10% - 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 against 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 10%

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47649-0101	
Route of Administration	DENTAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)		CARBAMIDE PEROXIDE	10 g in 100 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:47649-0101-2	4 in 1 PACKAGE	06/07/2015	
1	NDC:47649-0101-1	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(47649-0101)