DR.WHITISS 35% - 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.Whitiss 20% 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

n teeth. your custom on how to load our dentist's ins 3) F or one bulb 1/3 to 1/2 of th tray. Use no significant: nd consult occurs, stop t e tray firmly h over the teeth itening tray in ft toothbrush. gel with clean fir eteeth. Remov ed gel.) ice; do not swi 10% for 8-10 dentist, wear D ected otherwin % for 4-6 hours overnight, Dr.V ingredients. re allergic to a se this produc of the gums is, soreness, or occurs such or physician. rsult a dental pro discontinue us nildren under e not recommen containing per rsing women. f 18 and pregr e call Poison nount is swalliws vallow. If a sign 3. nmediately. irect sunlight. avoid storing pr of reach of chir nl mide Peroxide edients(w/w) AC

sook



DR.WHITISS 35%

carbamide peroxide gel, dentifrice

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:47649-1301

Route of Administration DENTAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength	
CARBAMIDE PERO XIDE (UNII: 31PZ2VAU81) (HYDROGEN PERO XIDE - UNII:BBX060AN9V)	CARBAMIDE PEROXIDE	35 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:47649-1301-2	4 in 1 PACKAGE	08/11/2015		
1	NDC:47649-1301-1	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	08/11/2015			

Labeler - Nibec Co., Ltd (687796909)

Registrant - Nibec Co., Ltd (687796909)

Establishment			
Name	Address	ID/FEI	Business Operations
Nibec Co., Ltd		687796909	manufacture (47649-1301)

Revised: 12/2018 Nibec Co., Ltd