

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.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





DR. WHITISS 35%

carbamide peroxide gel, dentifrice

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|-----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:47649-130 1 |
| 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 | 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:47649-130 1-2 | 4 in 1 PACKAGE | 08/11/2015 | |
| 1 | NDC:47649-130 1-1 | 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