NATORAL KOREAN GINSENG- menthol mouthwash Natoral Limited

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

Menthol 0.03%

Antigingivitis

Helps control plaque that leads to gingivitis.

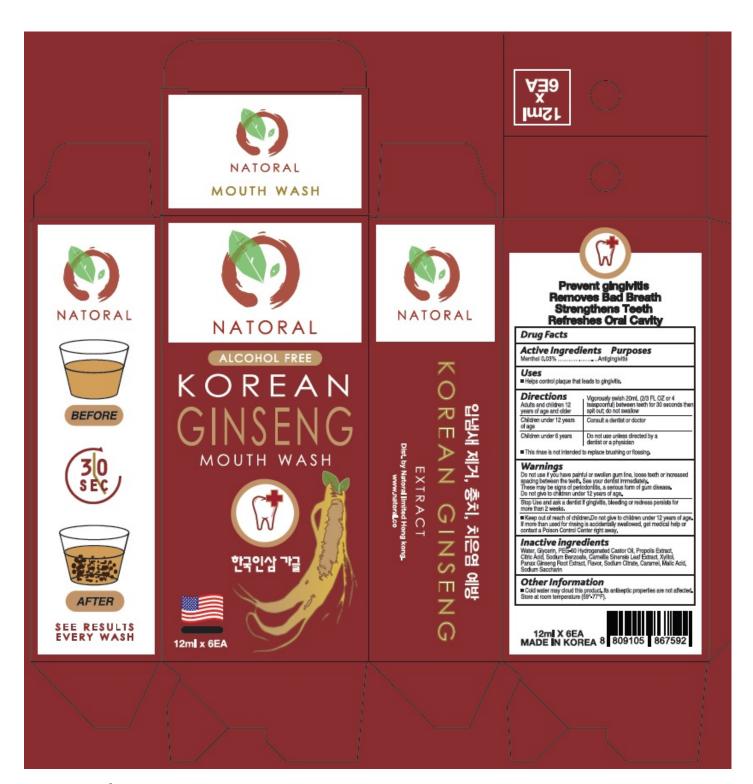
Adults and children 12 years of age and older Vigorously swish 20mL (2/3 FL OZ or 4 teaspoonful) between teeth for 30 seconds then spit out; do not swallow Children under 12 years of age Consult a dentist or doctor Children under 6 years Do not use unless directed by a dentist or a physician

- This rinse is not intended to replace brushing or flossing.
- Do not use if you have painful or swollen gum line, loose teeth or increased spacing between the teeth. See your dentist immediately. These may be signs of periodontitis, a serious form of gum disease. Do not give to children under 12 years of age.
- **Stop Use** and ask a dentist if gingivitis, bleeding or redness persists for more than 2 weeks.

Do not give to children under 12 years of age. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Water, Glycerin, PEG-60 Hydrogenated Castor Oil, Propolis Extract, Citric Acid, Sodium Benzoate, Camellia Sinensis Leaf Extract, Xylitol, Panax Ginseng Root Extract, Flavor, Sodium Citrate, Caramel, Malic Acid, Sodium Saccharin

12 mL Sachet x 6



260 mL Bottle





520 mL Bottle





NATORAL KOREAN GINSENG

menthol mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71211-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.3 mg in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6 A3C0 OX)				
PEG-60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)				
PROPOLIS WAX (UNII: 6 Y8 XYV2NOF)				
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)				
SO DIUM BENZO ATE (UNII: OJ245FE5EU)				
GREEN TEA LEAF (UNII: W2ZU1RY8B0)				
XYLITOL (UNII: VCQ006KQ1E)				
ASIAN GINSENG (UNII: CUQ3A77YXI)				
SO DIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
CARAMEL (UNII: T9D99G2B1R)				
MALIC ACID (UNII: 817L1N4CKP)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:71211-001-02	6 in 1 BOX	0 1/29 /20 17		
1	NDC:71211-001-01	12 mL in 1 POUCH; Type 0: Not a Combination Product			
2	NDC:71211-001-03	260 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 1/29 /20 17		
3	NDC:71211-001-04	520 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 1/29/20 17		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	0 1/29/20 17		

Labeler - Natoral Limited (664445977)

Registrant - Natoral Limited (664445977)

Establishment				
Name	Address	ID/FEI	Business Operations	
LCC Ltd		688785286	manufacture(71211-001)	

Revised: 2/2017 Natoral Limited