# NEW DOCTOR AG PLUS GOLD- sodium monofluorophosphate paste, dentifrice HANIL PHARMACEUTICAL 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.

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### **Drug Facts**

ACTIVE INGREDIENT: Sodium Monofluorophosphate

**INACTIVE INGREDIENTS:** 

D-Sorbitol, Glycerin, Sodium Saccharin, Chitosan, Xylitol, Sodium Lauryl Sulfate, Menthol, Peppermint, Sodium Benzoate, Green tea extract, Sodium Carboxyl Cellulose, Siver, Water, Triclosan, Siliccon Dioxide

PURPOSE: ANTICAVITY

WARNINGS:

WHEN USING THIS PRODUCT DO NOT USE FOR SENSITIVITY LONGER THAN FOUR WEEKS UNLESS RECOMMENDED BY A DENTIST. STOP USE AND ASK A DENTIST IF THE SENSITIVITY PROBLEM PERSISTS OR WORSENS. SENSITIVE TEETH MAY NEED PROMPT CARE.

KEEP OUT OF REACH OF CHILDREN:

IF ACCIDENTALLY SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

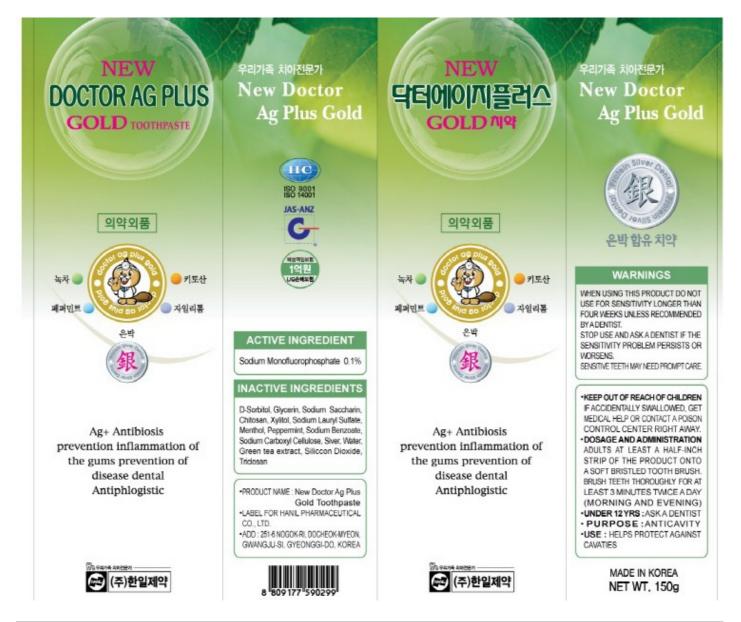
INDICATION AND USAGE:

ADULTS AT LEAST A HALF-INCH STRIP OF THE PRODUCT ONTO A SOFT BRISTLED TOOTH BRUSH. BRUSH TEETH THOROUGHLY FOR AT LEAST 3 MINUTES TWICE A DAY (MORNING AND EVENING) UNDER 12 YRS: ASK A DENTIST

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#### NEW DOCTOR AG PLUS GOLD sodium monofluorophosphate paste, dentifrice **Product Information Product** Type HUMAN OTC DRUG NDC:75984-001 Item Code (Source) **Route of Administration** DENTAL **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION -0.15 g SODIUM UNII:Q80VPU408O) **MONOFLUOROPHOSPHATE** in 150 g **Inactive Ingredients Ingredient Name** Strength GLYCERIN (UNII: PDC6A3C0OX)

X										
s	SO DIUM LAURYL SULFATE (UNII: 368 GB5141J)									
Μ	MENTHOL (UNII: L7T10EIP3A)									
PI	PEPPERMINT (UNII: V95R5KMY2B)									
s	SODIUM BENZOATE (UNII: OJ245FE5EU)									
SI	SILVER (UNII: 3M4G523W1G)									
W	WATER (UNII: 059QF0KO0R)									
Packaging										
#	Item Code	Package Description	Marketin	ıg Start Date	Ma	arketing End Date				
1	NDC:75984-001-01	150 g in 1 CARTON								
Marketing Information										
N	Aarketing Category	eting Category Application Number or Monograph Citation		Marketing Start Date		Marketing End Date				
0	TC monograph final part355			09/01/2010						

Labeler - HANIL PHARMACEUTICAL CO., LTD. (688197087)

### Registrant - HANIL PHARMACEUTICAL CO., LTD. (688197087)

## Establishment

Name	Address	ID/FEI	Business Operations
HANIL PHARMACEUTICAL CO., LTD.		688197087	manufacture

Revised: 2/2011

HANIL PHARMACEUTICAL CO., LTD.