AMHEALER- sodium fluoride spray HEALINGAM 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.

ACTIVE INGREDIENT

Active Ingredient: Sodium Fluoride 0.02%

INACTIVE INGREDIENT

Inactive Ingredients: Water, Thiobacillus

PURPOSE

Purpose: Bad breath removal

WARNINGS

Warnings: 1. Keep out of reach of babies and children 2. Keep away from direct sunlight

KEEP OUT OF REACH OF CHILDREN

1. Keep out of reach of babies and children

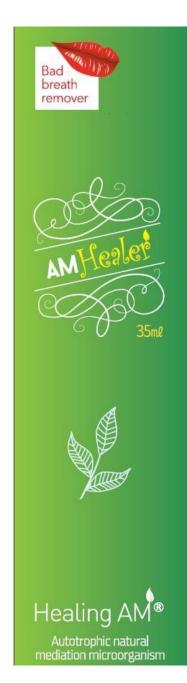
INDICATIONS & USAGE

Indications & Usage: Open the container cap and press the spray button(1~2 times)

DOSAGE & ADMINISTRATION

Dosage & Administration: Do not use more than 50 per day (50 times)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





- · Product Name AmHealer
- · Produced & Sales Healingam co., Itd
- · Produced in Republic of Korea
- · Net weight 35ml
- · Active Ingredient : Sodium Fluoride 0,02%
- · Inactive Ingredients : Water, Thiobacillus
- Purpose : Bad breath removal
- · Warnings:
- Keep out of reach of babies and children
- 2. Keep away from direct sunlight
- Indications & Usage:
 Open the container cap and press the spray button
 (1~2 times)
- Dosage & Administration:
 Do not use more than 5ml per day (50 times)



breath

remover







AMHEALER

sodium fluoride spray

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69890-010			
Route of Administration	ORAL					

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Sodium Fluoride (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.007 mg in 35 mL	

Inactive Ingredients

		Strength					
Water (UNII: 059QF0KO0R)							
Packaging							
# Item Code	Package Description	Marketing Start Date	Marketing End Date				
1 NDC:69890-010-01	35 mL in 1 CARTON; Type 0: Not a Combination Product						
Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	part355	05/01/2015					

Labeler - HEALINGAM CO., LTD (689514353)

Registrant - HEALINGAM CO., LTD (689514353)

Establishment						
Name	Address	ID/FEI	Business Operations			
HEALINGAM CO., LTD		689514353	manufacture(69890-010)			

Revised: 6/2015 HEALINGAM CO., LTD