

**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.*

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**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 5□ per day (50 times)

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**



Bad  
breath  
remover



35ml



Healing AM<sup>®</sup>  
Autotrophic natural  
mediation microorganism




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- Product Name AmHealer
- Produced & Sales  
Healingam co., Ltd
- Produced in Republic of Korea
- Net weight 35ml
- Active Ingredient :  
Sodium Fluoride 0,02%
- Inactive Ingredients :  
Water, Thiobacillus
- Purpose :  
Bad breath removal
- Warnings :  
1, 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)
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Do not use more than 5ml per  
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Bad  
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[www.healingam.com](http://www.healingam.com)

## AMHEALER

sodium fluoride spray

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:69890-010 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength          |
|--|-------------------|-------------------|
| <b>Sodium Fluoride</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION      | 0.007 mg in 35 mL |

### Inactive Ingredients

| Ingredient Name              |  | Strength   |                      |                    |
|------------------------------|--|--|----------------------|--------------------|
| Water (UNII: 059QF0KO0R)     |  |  |                      |                    |
| <b>Packaging</b>             |  |  |                      |                    |
| #                            | 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 |                      |                    |
| <b>Marketing Information</b> |  |  |                      |                    |
| 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