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Caries Control/Dentin Desensitizing Agent  
S A F O R I D E  
(Diamine Silver Fluoride solution)

Standard Commodity Classification No. of Japan
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872790
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Approval No.	(45AM)No.18
Date of listing in the NHI reimbursement price	Jan. 1970
Date of initial marketing in Japan	Feb. 1970

Storage : Preserve in tight, light-resistant polyethylene containers, in a cold place

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**【Description】**

1.Composition

SAFORIDE contains 380 mg of diamine silver fluoride in 1mL.

2.Description

SAFORIDE is a clear and colorless solution.

It has a faint odor of ammonia.

It is gradually affected by light or heat.

**【Indications】**

Arrestment of incipient caries, prevention of recurrent caries and desensitization of hypersensitive dentin

**【Dosage and Administration】**

1.Tooth surface cleaning

After completely removing debris from the tooth surface to be treated, cleanse thoroughly with oxydol.

2.Isolation and drying

Use a cotton roll to isolate the affected tooth from moisture. Use a saliva ejector in cases of high saliva flow.

After wiping away saliva with a cotton roll, thoroughly dry the tooth surface with an air syringe.

(If the surface to be treated is extremely close to the gingiva, isolate with a rubber dam or apply vaseline or similar material to the gingiva to prevent contact with SAFORIDE.)

### 3.Application of SAFORIDE

Apply a few drops(approx. 0.15 - 0.2mL) of SAFORIDE to a small cotton pellet and rub onto the treatment surface for 3 to 4 minutes. Increase or decrease the amount of SAFORIDE used according to the number and symptoms of teeth to be treated.

### 4.Post-application procedure

- 1) Removing        remove the cotton roll
- 2) Rinsing        rinse with water or saline solution

### 5.Treatment repetition

Normally the above procedure should be repeated 3 to 4 times at several-day intervals.

### (General Application Methods of SAFORIDE)

The method of application of SAFORIDE should be modified somewhat according to the indication.

#### A.Prevention and Arrestment of incipient caries in deciduous teeth

Remove carious enamel using a spoon excavator. Sectionally clean and dry the lesion using conventional methods. Apply SAFORIDE for 3 to 4 minutes according to the procedure in **【 Dosage and Administration 】** .

Repeat application 3 times with an interval of 2 to 7 days between each application.

The lesion should be examined(e.g. for hardness) once every 3 to 6 months.

Reapply SAFORIDE if necessary depending on the condition of the lesion. A slice-cut of the proximal surface will encourage self-cleaning action and improve the effect of SAFORIDE. Carry out restorative treatment if and when it becomes necessary.

#### B.Prevention of recurrent caries

Following preparation of cavities or abutment teeth, apply SAFORIDE 1 to 2 times according to **【 Dosage and Administration 】** .

#### C.Desensitization of hypersensitive dentin

Apply SAFORIDE to hypersensitive dentin 3 to 4 times at 2 to 3 day intervals according to the procedure in **【 Dosage and Administration 】** .

When preparing cavities or abutment teeth, apply SAFORIDE according to the procedure in **【 Dosage and Administration 】** and confirm the preparation has been desensitized. Proceed with excavation of soft dentin or preparation of the abutment tooth the following day or later.

## 【Precautions】

### 1. Careful Administration

SAFORIDE should be administered carefully in deep cavities as it may cause pulpal disorders. It is recommended that SAFORIDE be diluted before use in such cases.

### 2. Important Precautions

SAFORIDE should not be applied to permanent anterior teeth as its silver content will stain dentin a dark color.

### 3. Adverse Reactions

(1) Adverse reactions reported in a study of 58,615 teeth were:

Transient pain	0.11%(66 teeth)
Continuous pain	0.05%(28 teeth)
Pulpal damage	0.12%(69 teeth)

(2) Effects on the pulp

SAFORIDE will permeate tooth structure. Depending on the condition of the cavity. SAFORIDE may affect the pulp transiently. (Should pain occur after application, rinse immediately with water, saline solution or oxydol. If pain persists, apply dental-use phenol camphor.)

### 4. Precautions concerning Use

Accidental contact of gingiva or mucous membrane with SAFORIDE may cause corrosion. When applying SAFORIDE to areas near the gingiva, isolate the treatment surface with rubber dam to prevent accidental exposure. If rubber dam cannot be used, apply vaseline or cocoa butter to the gingiva before using SAFORIDE. (Should accidental contact occur, wash the mouth with water, saline solution or oxydol immediately.)

## 【Clinical Studies】

### 1. Arrestment of incipient caries

The application of SAFORIDE was shown to produce the greatest cariostatic effect, when compared to Howe's silver nitrate solutions, 8% stannous fluoride solutions and distilled water used as a control, in samples monitored over a 6 month period for percent change in caries progression.

### 2. Prevention of recurrent caries

In a study of deciduous carious teeth, SAFORIDE was applied following cavity preparation and prior to amalgam restoration. Examination after 2 years revealed no cases of recurrent caries.

### 3.Desensitization of hypersensitive dentin

In a study of patients displaying dentin hypersensitivity, the clinical effect of SAFORIDE and 50% silver nitrate solution were compared. Teeth treated with SAFORIDE exhibited a significantly greater degree of desensitization than those treated with silver nitrate(Fischer).

#### **【Pharmacology】**

SAFORIDE has been shown through various research and testing to have the effects of both the silver products(silver nitrate) and the fluoride products(sodium fluoride etc.)

#### **【Physicochemistry】**

Nonproprietary name: Diamine Silver fluoride  
Chemical name: Diamine Silver fluoride  
Molecular formula:  $\text{Ag}(\text{NH}_3)_2\text{F}$   
Molecular Weight: 160.93  
Description: Refer to **【Description】** 2.Dscription

#### **【Precautions for Handling】**

##### 1.Regulatory Classification

Powerful drug Designated drug

##### 2.Precaution in storage

- (1)Replace cap immediately after use
- (2)Use as soon as possible after opening

##### 3.SAFORIDE will stain skin, clothes and instruments brown or black. Refer to the following for stain removal.

###### (1)Skin

Wash immediately with water, soap solution, ammonia solution or iodine tincture and rinse thoroughly with water. Do not use excessive methods in an attempt to remove difficult stains from skin as the stains will eventually fade.

###### (2)Clothing/instruments

Same procedure as with stained skin.

##### 4.If SAFORIDE is dispensed into a separate container, be sure to wash or thoroughly wipe clean the container immediately after use.

**【Packaging】** 5mL bottle

**【References】**

- 1)Nishino, M.: J. Osaka Univ. Dent. Sch., 14: 1, 1969 (in Japanese)
- 2)Shimizu, A.: Japan J. Conserv. Dent., 17: 183, 1974.(in Japanese)  
Shimizu, A.: Dental Outlook, 45: 159, 1975.(in Japanese)
- 3)Aono, M. et al: Japan J. Conserv. Dent., 10: 31, 1967.(in Japanese)

**\* 【Requests of References】**

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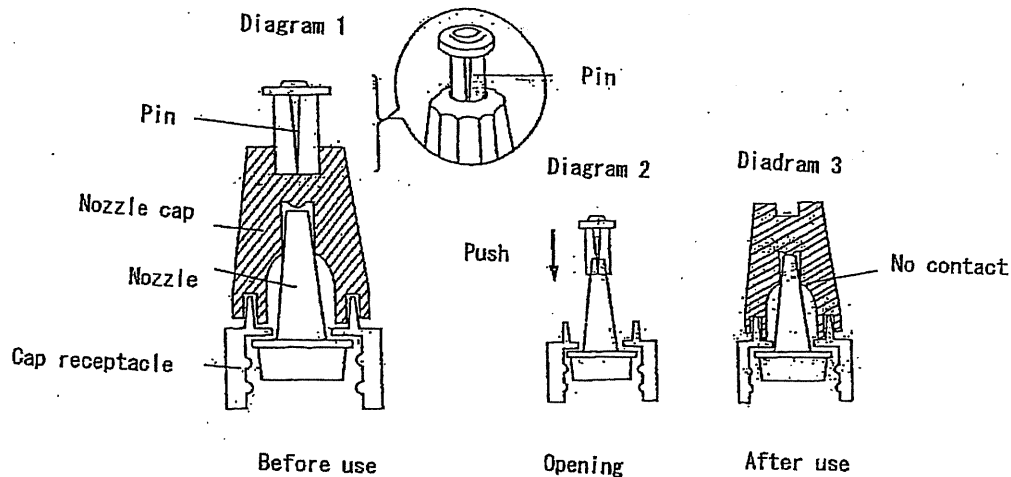
## Notes on SAFORIDE Container

### Bottle features

- 1.SAFORIDE's bottle features a drip-free nozzle and a cap with a spillage reservoir for dual protection from external leakage.(Diagram 1)
- 2.The external rocket-shaped container has a broad base for stability.  
SAFORIDE's bottle may be used from within this container.

### Dispensing method

- 1.Tap the nozzle a few times to displace any liquid accumulations.
- 2.Push the pin on the top of the nozzle. Do not squeeze the bottle when pushing.  
(Diagram 2)
- 3.The nozzle cap will not contact the nozzle tip after it has been replaced on the bottle, so liquid will not leak down the inner surface of the tap.  
(Diagram 3)



### Additional

- 1.Wash the nozzle cap after using it as a receptacle.
- 2.Wipe off any liquid collected in the cap receptacle before replacing the nozzle cap.
- 3.Ensure no liquid has leaked onto contact surfaces of the outer container and nozzle cap.