

\*\*Revised: Nov. 2005(3rd version)

\*Revised: Jan. 2004

Root canal Treatment Agents  
S A F O R I D E • R C  
(Diamine Silver Fluoride solution)

Standard Commodity Classification No. of Japan
872790

Approval No.	(54AM)No.676
Date of listing in the NHI reimbursement price	Sep. 1981
Date of initial marketing in Japan	Oct. 1981

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

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**【Description】**

1.Composition

SAFORIDE RC contains 38 mg of diamine silver fluoride in each mL.

2.Description

SAFORIDE RC is a clear and colorless solution.

It has a faint odor of ammonia.

It is gradually affected by light or heat.

**【Indications】**

Root canal treatment ( Disinfection )

**【Dosage and Administration】**

1. After enlarging of the root canal and cleaning, inserts a few drops of SAFORIDE RC to a cotton plug or paper-point in the root canal, and seales it temporarily.
2. The above-mentioned treatment is repeated until the bacterial culture test in the root canal is presented a negative sign.

**【Precautions】**

1.Careful Administration

- (1)Case of over instrumentation
- (2)Incompleted teeth of root formation
- (3)Incompleteted closing of root apex and/or tooth of large apical foramen

2.Important Precautions

SAFORIDE RC should be careful about application to root canal of anterior teeth as its silver content will stain dentin a dark color.

3.Adverse Reactions

(1)Adverse reactions reported in a study of 1,780 patients(2,492 teeth) , including the report of the incidence of Adverse reactions, were:

Transient pain	2.3%(57 teeth)
Continuous pain	2.3%(57 teeth)
Incompatibility	1.7%(43 teeth)
Black stained tooth	27.1%(675 teeth)

(2)Others adverse reaction

1)inside of root canal

SAFORIDE RC may be stained root canal wall of dentin because its silver content is composed

2)periodontal membrane

When(if) SAFORIDE RC is leaked outside of root canal , this is disturbed the apical periodontal tissues , and may sometimes be caused transient pain, continuous pain and incompatibility( should be treated with the medicine after performing the root canal preparation method which is formed apical sheet

4.Precautions concerning Use

Accidental contact of gingiva or mucous membrane with SAFORIDE RC may cause corrosion. When applying SAFORIDE RC 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 RC. (Should accidental contact occur, wash the mouth with water, saline solution or oxydol immediately.)

**【Clinical Studies】**

1. Clinical effect for the infected root canal showed stump of tooth

1-2 weeks after filling	2 months after filling	total
49 teeth effect 73.5(%)	35 teeth effect 91.4(%)	49 teeth effect 85.7(%)

## 2. Clinical effect for the infected root canal

Results of the bacterial culture examination	Disappearance of the percussion pain	Disappearance of the exudating liquid
48 teeth negative 70.8(%)	50 teeth effect 84.0(%)	50 teeth effect 88.0(%)

### 【Pharmacology】

#### 1. Bactericidal effects

SAFORIDE RC showed the antibacterial activity almost equal to CMCP(Camphorated paramonochlorophenol) for Streptococcus mitis S.73strain, Staphylococcus aureus 209P strain, Escherichia coli S.21strain, Corynebacterium xerosis S.33strain (Department of endodontics, OSAKA DENTAL UNIVERSITY)

#### 2. Persistency of Bactericidal effects

We were recognized persistency of bactericidal effect culture after 1week (Department of endodontics, TOKYO MEDICAL AND DENTAL UNIVERSITY)

#### 3. Coating experiment of root canal wall of the extracted tooth

##### (1)Scanning electron microscopic observation

1)Opening part of dentinal tubule was able to be closed 3 times by application almost , and the tube blockage was admitted obturator

2)Depth of that the cristalloid substace (It is assumed Ag<sub>2</sub>PO<sub>4</sub>) in dentinal tubule produces reach to the vicinity of dentino-cemental junction, and then exceeds more than the distance to which microbial is assumed to invade it. therefore, Bactericidal effect of SAFORIDE RC that is proven

(Department of endodontics, THE NIPPON DENTAL UNIVERSITY)

##### (2)Dye infiltration experiment to dentinal tubule of root canal wall

3 times application of SAFORIDE RC was inhibited dye infiltration as same potency as 2 times application of SAFORIDE. effect of dentinal tubule block of this product was recognized (Department of endodontics, THE NIPPON DENTAL UNIVERSITY)

#### 4. Experiment for hard tissue powder of tooth

##### (1)Anti-decalcification experiment

Anti-decalcification potency of SAforide RC against synthetic hydroxyapatite is same degree to 1.1% NaF(F ion concentration is same), but its of silver ammonia solution with same silver ion concentration has no anti-decalcification potency ,therefore , Anti-decalcificationpotency has be caused only F-ion(Department of endodontology, OSAKA DENTAL UNIVERSITY)

##### (2) X-ray diffraction pattern study

Diffraction patarn which is acted synthetic hydroxyapatite and dentin powder SAFO RIDE RC is confirmed no change of apataite structure(Department of endodontology, OSAKA DENTAL UNIVERSITY)

**【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.Description

**【Precautions for Handling】**

1.Precaution in storage

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

2.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(disappear).

(2)Clothing/instruments

Same procedure as with stained skin.

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

**【Packaging】** 5mL bottle

**【References】**

- 1)Suzuki, K. et al: Dental Outlook, 43: 99, 1974 (in Japanese)
- 2)Hori, N. et al: Dental Outlook, 46: 495, 1975.(in Japanese)
- 3)Sekine, I. et al: Dental Outlook, 52: 725, 1978.(in Japanese)
- 4)Matsuda, T. et al: SHIKAIGAKU, 35: 679, 1972.(in Japanese)
- 5)Katsuumi, I.: SHIGAKU, 65: 934, 1978.(in Japanese)
- 6)Nagao, K.: SHIKAIGAKU, 42: 413, 1979.(in Japanese)

**\*\* 【Requests of References】**

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\*\*\* Manufactured and Distributed by: TOYO SEIYAKUKASEI CO.,LTD.

2-5-4, Tsurumi, Tsurumi-ku, Osaka, Japan

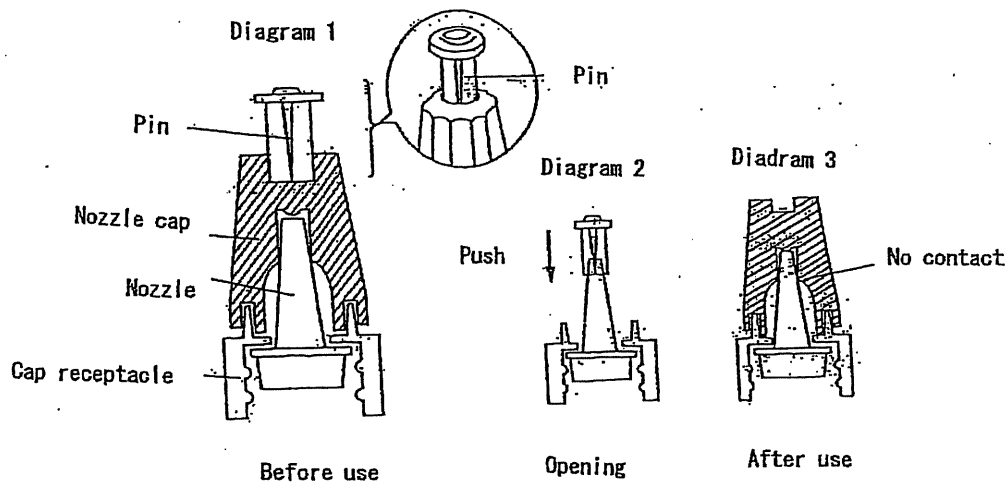
## Notes on SAFORIDE RC Container

### Bottle features

- 1.SAFORIDE RC'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 RC'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. (Diagram 2)  
Do not squeeze the bottle when pushing.
- 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.