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Prepared : July 2004

Caries preventing agents/ Tooth surface coating agents

Fluor·Jelly

(Acidulated phosphate fluoride jelly)

Standard Commodity Classification No. of Japan
872790

Approval No.	14300AMZ01798000
Date of listing in the NHI reimbursement price	July 2004
Date of initial marketing in Japan	Sep. 2004

Storage : Preserve in tight, light-resistant plastic containers,

【Description】

1.Composition

Active Ingredient	20 mg of Sodium Fluoride in 1g.
Inactive Ingredients	Carmellose Sodium, Saccharin Sodium, Cetylpyridinium Chloride, Phosphoric Acid, Concentrated Glycerin, Perfume, Titanium Oxide

2.Description

This product is a white and viscous liquid.

It has a acidity taste and a sweet taste, and has a slightly odor.

【Indications】

Prevention of dental caries

【Dosage and Administration】

Usually, the topical application for the tooth surface is to be performed 1 ~ 2 times a year as follows:

< Application Procedures >

1. Ordinary methods

(1) Tooth surface cleaning

After cleaning the teeth and the inside of the mouth sufficiently with a toothbrush etc., remove any tartar on the coating surface if necessary and then remove the dental plaque from the tooth surface using a brush or polishing cup with the abrasive.

(2) Moisture control and drying

Isolate the teeth using rolled cotton, wipe the saliva away with a cotton wads and then dry with compressed air.

(3) Application of Jelly

Apply the coating agent to the tooth surface for as long a time as possible using absorbent cotton, gauze soaked thoroughly in the coating agent jelly (2 mL or less).

Avoid mouthrinsing for about 30 minutes after application and spit out only the saliva.

2. Tray methods

(1) Tooth cleaning

Clean the teeth as in the ordinary methods.

(2) Selection and fitting of Tray

Select a tray which fits the general shape of the teeth and apply a rubber bag and coating paper to fit the size of the tray.

(3) Apply of Jelly

Apply the coating agent to the coating paper using a dropper (2 mL or less).

(4) Setting of Tray

Insert the tray in the mouth and fit it lightly over the teeth for about 4 minutes.

(5) Removal of Tray

Remove the tray and the coating paper.

Avoid mouthrinsing for about 30 minutes after application and spit out only the saliva.

【Precautions】

1. Important precautions

Volume of the coating agent jelly should be 2 mL or less .

In pediatric patients, application with this jelly should be limited to the minimum dose (volume).

2. Adverse Reactions

This product has not been investigated to determine the incidence of adverse reactions.

	The incidence could not determined
Hypersensitivity	Hypersensitivity reactions had been reported. Application should be discontinued immediately if such symptoms are observed

3. Precautions concerning Use

- 1) Only use for prevention (topical application) of dental caries.
- 2) Because of the corrosive action, this jelly should not be contacted with oral mucous membrane.
- 3) Avoid mouthrinse for 30 minutes after application, spit out the remaining saliva that contains this jelly, and do not swallow the jelly.
- 4) If this jelly has been ingested accidentally, the acute toxic symptoms (eg., vomiting, stomachache and diarrhea etc.) induce, give Milk, Calcium compounds (eg., calcium gluconate) in the emergency

and then receive the doctor's diagnosis and treatment.

5) Only use dentist or dental hygienist under the direction of the dentist.

4. Other precautions

In vitro studies have been reported that titanium, titan alloy(Ti-6Al-4V) or silica containing materials (dental glassionomercements, dental composite resin filling materials etc.) could be discolored or affected on their surface propaties, when contact with this agent ^{2, 3)}.

【Physicochemistry】

Nonproprietary name : Sodium Fluoride

Molecular formula : NaF

Molecular Weight : 41.99

Description : NaF occurs as a white crystalline powder. It is a odorless.
It is a soluble in water.

【Precautions for Handling】

Refer to " Storage "

【Packaging】

100g in tube

【References】

1) Horie K. etc.: Yokenn-nennpou: 260, 1958

2) Ozeki K. etc.: Sikuwa Gakuho, 96(4): 293, 1996

3) Anndo Y. : Japan J. Conserv. Dent., 33(3): 690, 1990

* 【Requests of References】

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