

**Revised:July 2009(6th version)

*Revised:Mar. 2008

Prevention of Dental Caries/Mouthrinsing Agent

** M I R A N O L Granules 11%

** Powerful drug

Standard Commodity Classification No. of Japan
87279

	Approval No.	21700AMZ00612
**	Listing in the NHI reimbursement price	Out of listing in the NHI reimbursement price
	Date of initial marketing in Japan	May 1968
	Date of latest reevaluation	July 1985

Storage : Preserve in tight, light-resistant containers,
i* Expiration date : Indicated on the container

【Description】

1.Composition

Active Ingredient	110 mg of Sodium Fluoride in 1g.
Inactive Ingredients	D-Mannitol, Xylitol, Macrogol 6000, Sodium Dihydrogen Phosphate Dihydrate, Cetylpyridinium Chloride, Ethyl Parahydroxybenzoate, Propyl Parahydroxybenzoate, Hydroxypropylcellulose, Cinnamon Oil, l-Menthol, Perfume

2.Description

This product is a white granule.

It has a odor.

【Indications】

Prevention of dental caries

【Dosage and Administration】

Usually, use of 5 ~ 10mL of 0.05 ~ 0.1% solution of NaF, once a day after meals or before bedding mouthrinses in a following way.

Mouthrinsing method

The solution is kept in the mouth, rinsing is performed for about 30 seconds so that the solution can go around the tooth surface sufficiently, and then the solution is expectorated sufficiently.

The volume of one time may be increased or decreased according to age and oral size.

In general, in the case of an under school-age is received 5mL, and a school-age or an over school-age are received 7-10 mL.

(General Mouthrinsing Methods)

A.Preparing Method of the mouthrinsing solution

This product is a water-soluble granule, so add water, dissolve easily by mixing, and is the mouthrinsing solution with a colorless and a odor.

Concentrations of Sodium Fluoride of MIRANOL are following.

Amount of MIRANOL	Vol.of Water	Mouthrinsing solution		
		Conc.of NaF	Conc.of F	NaF/1mL
1.8g/1pack(pink pack)	200mL	0.099%	450ppm	0.99mg
1g/1pack(yellow pack)	200mL	0.055%	250ppm	0.55mg

Dissolving·preserving of the mouthrinsing solution are used in plastic containers.

B.Mouthrinsing (mouthwashing) method

- 1)The solution is kept in the mouth, rinsing is performed with lips tightly closed for about 30 seconds so that the solution can go around the tooth surface sufficiently.
- 2)The face is turned below because it doesn't swallow and it mouthrinses.
- 3)After mouthrinsing, the solution is expectorated sufficiently. Then, if the saliva collected can be expectorated 1-2 portions, it is not necessary to be mouthrinsed by water.
- 4)The teeth are brushed or the mouth is washed by water before mouthrinsing.
- 5)The liquid amount of one time is not kept in the mouth, divided into two portions. (Liquid that remains after the liquid is measured and is kept in the mouth is thrown away)

【Precautions】

1.Adverse Reactions

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

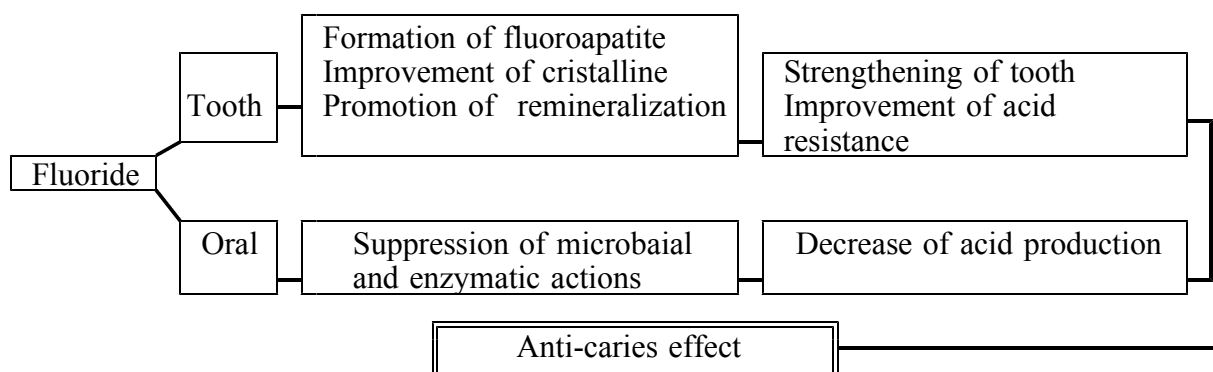
	The incidence could not determined
Hypersensitivity	Hypersensitivity reactions had been reported. Mouthrinsing should not discontinued immediately if such symptoms are observed

2.Precautions concerning Use

- 1) Only use for prevention(mouthrinsing) of Dental Caries.
- 2) Do not swallow the mouthrinsing solution.
- 3) Do not use for infants that is possible to ingest the mouthrinsing solution.
- 4) If large amounts of this product 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) Use under the direction of the dentist.

【Pharmacology】

Mechanism of Caries-prevention of Fluoride ¹⁾



【Physicochemistry】

Nonproprietary name: Sodium Fluoride

Molecular formula: NaF

Molecular Weight: 41.99

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

【Precautions for Handling】

** 1.Regulatory Classification

Powerful drug

2.Others

Dissolving・preserving of the mouthrinsing solution are used in plastic containers

【Packaging】

1g x 9packs, 90packs, 180packs

1.8g x 90packs, 180packs, 450packs

【References】

- 1) The Committee of fluoride application study: Fluoride application and health -Caries preventive effect and safety-(in Japanese), Oral Health Association of Japan, Tokyo, 1998.

* 【Requests of References】

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