**Revised:Oct. 2006(4th version)
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Intraoral Topical Hemostatic Agent

Dental TDZett Jelly

Powerful drug, Designated drug and *Prescription drug[note)]

Standard Commodity Classification No. of Japan
872790

Approval No.	(61AM)No.3444
Listing in the NHI reimbursement price	Nov. 1986
Date of initial marketing in Japan	Dec. 1986
Date of latest reezamination	Jan. 1989

Storage : Preserve in tight, light-resistant containers,
*[note)]Caution : Use only pursuant to the prescription of a physician, etc.

【Contraindications (Dental TDZett Jelly is contraindicated in the following patients)】
Patients with a history of hypersensitivity to lidocaine or local amide anesthetics.

【Description】
1.Composition

Active Ingredient	25 g of Aluminum Chloride, 0.5 g of Cetylpyridinium Chloride and 5.25 g of Lidocaine(JP) in 100g.
Inactive Ingredients	Ethanol, Hydroxyethylcellose, Saccharin Sodium hydrate, Perfume

2.Description
This product is a colorless-yellowish, viscosous liquid.
It has a odor.
It has an acid taste.
It has an astringent, characteristic taste.

【Indications】
For Dental
Hemostasis of minor bleeding on oral mucous membranes.

【Dosage and Administration】
An appropriate amount(dosage) of Dental TDZett Jelly is applied to the bleeding area.

【Precautions】
1.Important precautions
(1)Do not apply the liquid of the overamount.
(2)Do not apply the liquid to a mucous membrane except the bleeding part.
(3)Do not swallow the liquid.
(4)Because contain lidocaine, observe the following point:
1)In rare instances this product may cause shock. Always be prepared to provide appropriate emergency measures should this occur.
2)Examine the patients overall physical condition to determine the likehood of shock.

2.Adverse Reactions
(1)In investigations conducted at the time of approval (63patients, 67 parts) and reexamination(556patients, 752parts) , adverse reactions to this product were reported.

gingival recession	5 (0.61%)	(parts)
redness	6 (0.73%)	(parts)
gingival pain	1 (0.12%)	(parts)

(2)Clinically significant adverse reactions.
1)Shock
Shock may develop. Patients must therefore be carefully monitored. If decreased blood pressure, pallidity, abnormal pulse or respiratory depression are observed, administration should be discontinued immediately and appropriate measures must be taken.
2)Central nerve
Toxic symptoms such as tremor or convulsion may develop. Patients must therefore be carefully monitored. If such symptoms are observed, administration should be discontinued immediately and appropriate therapeutic measures such as diazepam or very brief acting barbituric acid (e.g. sodium thiopental) must be taken.

**(3)Other adverse reactions

	The incidence could not determined
Central Nervous System	Sleepiness, Anxiety, Excitation, Blurred vision, Cvertigo, etc.
Gastrointestinal	Naurea・Vomiting etc.
Hypersensitivity	Dermatosis such as urticaria, etc, Edema, etc

If such symptoms are observed, these symptoms may be shiftted to shock or intoxication. Patients must therefore be carefully monitored and if it is necessary, appreciate measures must be taken.

3.Precautions concerning Use

Only for dental use

【Clinical studies】

1. Clinical effect of dental TDZett Jelly

	A reduction of the subgingival tooth sturucture	Removal of the rubber dam	Extraction of primary teeth
Dept.Ped.Dent. Osaka Univ. Sch. of Dent. [1)]	100% (24/24)		
Dept.Ped.Dent. Osaka Dent. Univ. [2)]	100% (18/18)	100% (16/16)	77.8% (7/9)
Dept.Ped.Dent. Aichi-Gakuin Univ.Sch. of Dent. [3)]	92% (46/50)		

2. Post-Marketing surveillance study

Effective rate 95.2% (638/670)

【Pharmacology】

(1) Hemostatic effect

a) Examination of coagulation time

In an examination using guinea-pig blood, Dental TDZett Jelly had a blood coagulation time of 60 to 90sec.

b) Hemostatic effect on experimentally induced oral membrane wounds

In an examination using rats, Dental TDZett Jelly was showed hemostasis in 30 sec. or less.

【Physicochemistry】

Nonproprietary name: Aluminum Chloride

Molecular formula: $AlCl_3 \cdot H_2O$

Molecular Weight: 241.43

Description: Aluminum Chloride occurs as a white to yellowish crystalline powder.
It is odorless.
It has an astringent and characteristic taste.
It is very soluble in water, freely soluble in ethanol(95), and soluble in glycerine.
It is deliqescent.

Nonproprietary name: Cetylpyridinium Chloride

Molecular formula: $C_{21}H_{38}ClN \cdot H_2O$

Molecular Weight: 358.00

Description: Cetylpyridinium Chloride occurs as a white crystals or crystalline

powder.
It is odorless, or a slight and characteristic odor.
It has a bitter taste.
It is freely soluble in water, in ethanol(95) and in chloroform, and practically insoluble in acetone.

Melting point: 80-84 ° C

Nonproprietary name: Lidocaine
Molecular formula: $C_{14}H_{22}N_2O$
Molecular Weight: 234.34
Description: Lidocaine occurs as a white to pale yellow crystals or crystalline powder.
It is very soluble in methanol and in ethanol(95), freely soluble in acetic acid(100) and in diethyl ether, and practically soluble in water.
It dissolves in dilute hydrochloric acid

Melting point: 66-69 ° C

* 【Precautions for Handling】
Regulatory Classification
Powerful drug, Designated drug and Prescription drug

【Packaging】
10 g bottle

【References】
1)Oyazato Y. etc.: Japan J. Ped. Dent., 556: 1982, 1982.
2)Ochiai N. etc.: Dental Outlook(SHIKAITENBOU), 62: 401. 1983.
3)Fukuta O. etc.: Dental Outlook(SHIKAITENBOU), 62: 1261. 1983.

* 【Requests of References】
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