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Intraoral Topical Hemostatic Agent

Dental TDZett

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

Standard Commodity Classification No. of Japan
872790

Approval No.	(58AM)No.448
Listing in the NHI reimbursement price	March 1983
Date of initial marketing in Japan	Sep. 1983
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 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 100mL.
Inactive Ingredients	Ethanol

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

【Indications】
Use for topical hemostasis in follwing cases:
1) Gingival retraction during subgingival preparation of a abutment tooth, cavity preparation, and impression taking
2) Gingivoplasty

【Dosage and Administration】
An appropriate amount(dosage, volume) of Dental TDZett 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 (195patients, 264 parts) and reexamination(3480patients, 4093parts) , adverse reactions to this product were reported.

nausea	1 (0.03%)	(patients)
gingival recession	8 (0.18%)	(parts)
redness	26 (0.60%)	(parts)
gingival pain	1 (0.02%)	(parts)
irritation	1 (0.02%)	(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
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

Institution	Effective rate (cases/ total cases)	
2nd. Dept. Concerv., Gifu dent. Univ.	100%	(81/81)
1st. Dept. Concerv., Kyusyu Univ. Sch. of Dent.	100%	(73/73)
Dept. Prosth., Osaka dent.Univ.	97.8%	(45/46)
Dept. Prosth., Kanagawa dent. Univ.	97.5%	(39/40)
Dentistry,Osaka kaisei Hospital	95.8%	(23/24)

2. Comparison of hemostatic effect of dental TDZett and 0.1%adrenaline solution
(Dept. 2nd. Concerv., Gifu dent. College)
In the hemostatic study, this drug was a significant difference ($p<0.01$) from 0.1% adrenaline solution.

3. Post-Marketing surveillance study
Effective rate 94.3% (2598/2756)

【Pharmacology】

(1) Hemostatic effect

a) Examination of coagulation time
In an examination using guinea-pig blood, Dental TDZett had a blood coagulation time of 60sec. or less, which was 1/15 the coagulation time of 25% aluminum chloride solution. (Dept. 2nd. Concerv., Gifu dent. College)

b) Hemostatic effect on experimentally induced oral membrane wounds
In an examination using rats, Dental TDZett was showed hemostasis in 10 seconds-an exceptionally rapid effect compared with 30 to 60 seconds required to show hemostasis with 25%aluminum chloride solution. (1st. Dept. Concerv., Kyusyu Univ. Sch. of Dent.)

(2) Local anesthetic effect
In a reflex test on rabbit optic mucous membranes, Dental TDZett showed a level of anesthetic effect roughly equal to that of 6% lidocaine hydrochloride solution. (Dept. 2nd. Concerv., Gifu dent. College)

(3) Antibacterial effect

a) Using Staphylococcus aureus, the phenol coefficient of Dental TDZett was measured to be 13. (Dept. 2nd. Concerv., Gifu dent. College)

b) In a test of antibacterial effect against oral flola (aerobic and anaerobic), Dental TDZett showed about 80% of the antibacterial effect of the dilute iodine tincture . (Dept. 2nd. Concerv., Gifu dent. College)

【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 mL bottle

【References】

1)Sekine I. etc.: Dental Outlook(SHIKAITENBOU), 56: 173, 1980.
2)Maeda K. etc.: Dental Outlook(SHIKAITENBOU), 55: 943. 1980.
3)Okuda T. etc.: Dental Outlook(SHIKAITENBOU), 56: 867. 1980.
4)Katsura I. etc.:Dental Outlook(SHIKAITENBOU), 56: 1069. 1980.
5) Shimada S. etc.:Dental Outlook(SHIKAITENBOU), 57: 189. 1981.

* 【Requests of References】

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