

BEFORE THE NEVADA STATE BOARD OF DENTAL EXAMINERS

IN REGARDS TO THE MATTER OF:

RDH, Redwine's request for the Advisory Opinion regarding the use of Orafix by a licensed dental hygienist pursuant to NAC 631.210 when the dentist is not present in the office

AO-1115-05

On November 5, 2005, pursuant to agenda item 4 (d) at a properly noticed meeting held at the Nevada State Board of Dental Examiners ("Board") office located at 6010 S Rainbow Boulevard, Suite A-1, Las Vegas, Nevada 89118 the "Board" issued the following advisory opinion.

Dr. Tony Guillen	Present
Dr. Rick Thiriot	Present
Dr. William O'Gara	Present
Dr. Donna Hellwinkel	Present
Dr. Michael Lloyd	Present
Dr. William Pappas	Present
Dr. Joel Glover	Present
Mrs. Roseanne Matthews	Present
Mrs. Sharon Peterson	Present
Mrs. Bonnie Bryan	Present

I.
BACKGROUND

1. As set forth in NAC 631.279 through authority of NRS 631.190 and NRS 233B.120 the Board is authorized to provide advisory opinions.

II. REQUESTED OPINION

Pursuant to NAC 631.279, Nevada licensee, Stephanie Redwine, RDH, has requested an advisory opinion regarding the use of Oraqix by a licensed dental hygienist pursuant to NAC 631.210 when the dentist is not present in the office.

2. Public notice of the above-referenced request for an advisory opinion was provided in accordance with state law.

III. DISCUSSION

Ms. Redwine requested this advisory opinion as to whether a licensed dental hygienist can use Oraqix when the employing dentist is not present in the office.

Board Counsel explained to the Board Members NAC 631.279 with regards to an advisory opinion, the process to proceed, and how to bring the motion forward. Board Member Peterson explained pursuant to NAC 631.210(1)(m) which permits the administration of topical anesthetic. Board Member Hellwinkel asked about topic versus local anesthetic. Board member Peterson explained the manufacturer's guidelines regarding maximum dosage. Board Members Pappas and Lloyd believed this product was topic.

NAC 631.279 Proceedings to determine applicability and construction of statutes and regulations. (NRS 631.190)

1. Any applicant or licensed dentist or dental hygienist may obtain a determination or advisory opinion from the Board as to the applicability of any provision of chapter 631 of NRS or any regulation adopted pursuant thereto by bringing an action for a declaratory judgment before the Board.

2. The Board will construe any statute or regulation reviewed pursuant to this section in a manner consistent with the declared policy of the State of Nevada.

IV.
CONCLUSION

After considering and discussing public comment pursuant to the authority set forth in NAC 631.279, NRS 631.190 and NRS 233B.120,

“That the Board issues an Advisory Opinion, the use of the product Oraqix which is a topical anesthetic by a licensed dental hygienist is permissible under NAC 631.210(1)(m).

ADVISORY OPINION

The motion was passed by majority of Board Members and the following Advisory Opinion is hereby issued by the BOARD:

- 1). That the use of the product Oraqix which is a topical anesthetic by a licensed dental hygienist is permissible under NAC 631.210(1)(m).

SO ORDERED:

Kathleen Kelly, Executive Director
Nevada State Board of Dental Examiners

Kathleen

From: [Redacted]
Sent: Tuesday, October 18, 2005 10:37 PM
To: Board of Dental Examiners
Subject: Re: Regarding Oraqix

Hi Kathleen,

Thank you for putting this on the agenda - it's always good to have the official opinion.

Oraqix is an anesthetic that is administered directly into the sulcus (no injection). It is Lidocaine and Prilocaine in a 1:1 mixture. One cartridge will deliver 42.5 mg of each drug, each cartridge is 1.7mL. The maximum recommended dose in one treatment session is 5 cartridges.

The package insert is available at www.oraqix.com if more information is desired by the board.

Thank you,

Stephanie

----- Original Message -----

From: Board of Dental Examiners
To: Stephanie Redwine
Sent: Monday, October 17, 2005 9:31 AM
Subject: RE: Regarding Oraqix

Stephanie:

Please provide more information about "Oraqix". As you are asking for an opinion of the Board, I will present your request to the members at our next board meeting to be held in November. If you are asking for guidance in the interim, I refer you to NAC 631.210 section (m) and discussion with the licensed dentist regarding his/her full understanding of the use of this pharmaceutical agent by a hygienist in his/her employ with a permit by this Board to administer local anesthesia.

Sincerely,

Kathleen J. Kelly
Executive Director
NSBDE
6010 S. Rainbow Blvd, Suite A-1
Las Vegas, NV 89118
(702) 486-7044

-----Original Message-----

From: Stephanie Redwine [mailto:slredwine@cox.net]
Sent: Sunday, October 16, 2005 7:57 PM
To: Board of Dental Examiners
Subject: Regarding Oraqix

Hi,

My name is Stephanie Redwine and I am a member of the Board of Trustees of the Nevada Dental Hygienists' Association (NDHA). I would like permission to put the answer to the following question on

Kathleen [REDACTED]

From: [REDACTED]

Sent: Sunday, October 16, 2005 7:57 PM

To: Board of Dental Examiners

Subject: Regarding Oraqix

Hi,

My name is Stephanie Redwine and I am a member of the Board of Trustees of the Nevada Dental Hygienists' Association (NDHA). I would like permission to put the answer to the following question on our NDHA website so that all hygienists in the state have access to the official position.

I have heard many opinions on the use of Oraqix and if a hygienist is allowed to use it when the dentist is not in the office.

What is the official position on the use of Oraqix when the dentist is out of the office (provided all other patient criteria is met as far as patient of record and seen within the last 18 months by the dentist)?

Please send the answer to me at s [REDACTED]

Thank you,

Stephanie Redwine, RDH, BS

10/17/2005

oraqix[®]
 (lidocaine and prilocaine
 periodontal gel) 2.5% / 2.5%

needle-free
 dental anesthesia



Don't get stuck
 without it!



professional portal 

the needle-free
 option for SRP

patient portal 

Oraqix[®] Dental Professional Portal

The Oraqix[®] Dental Professional Portal is for use by dental professionals. The information contained in this section is taken directly from the Oraqix[®] Prescribing Information and Oraqix[™] Dispenser full Directions for Use. This website is not for medical emergencies. Do not use this website for adverse event reporting. If you are a dentist/physician, follow the regulations required by your country's regulations.

Oraqix[®] Patient Portal

The Oraqix[®] Patient Portal introduces dental patient first FDA approved subgingival anesthetic, Oraqix[®] . provides an overview of oral care and gum disease. (lidocaine and prilocaine periodontal gel) 2.5%/2.5% novel liquid oil non-injectable anesthetic that allows to experience needle-free scaling and/or root planing procedures. Oraqix[®] does not prevent gum disease periodontitis.

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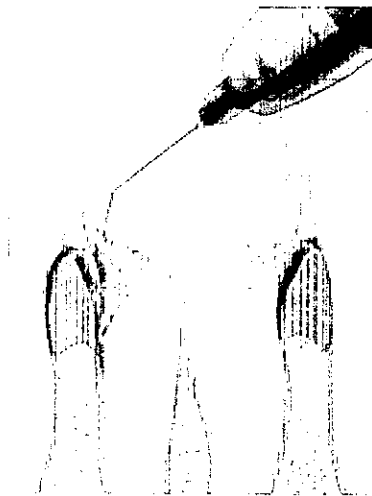
Oraqix® Administration

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Preparation, Application,

Dispenser F

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Patented thermosetting properties keeps Oraqix® in place during treatment

PRODUCT CHARACTERISTICS

Oraqix® Administration Flexibility

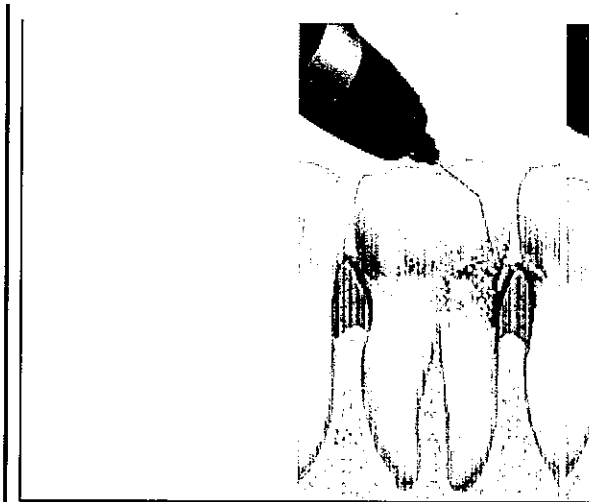
In many states, Oraqix® can be applied by dental hygienists. Please refer to the rules and regulations of each state dental board.

Apply Oraqix on the gingival margin around the selected teeth using the blunt-tipped applicator included in the package. Wait 30 seconds, then fill the periodontal pockets with Oraqix using the blunt-tipped applicator until the gel becomes visible at the gingival margin. Wait another 30 seconds before starting treatment. A longer waiting time does not enhance the anesthesia. Anesthetic effect, as assessed by probing of pocket depths, has a duration of approximately 20 minutes (individual overall range 14 - 31 minutes). If the anesthesia starts to wear off, Oraqix may be re-applied if needed. The maximum recommended dose of Oraqix at one treatment session is 5 cartridges, i.e., 8.5g gel.

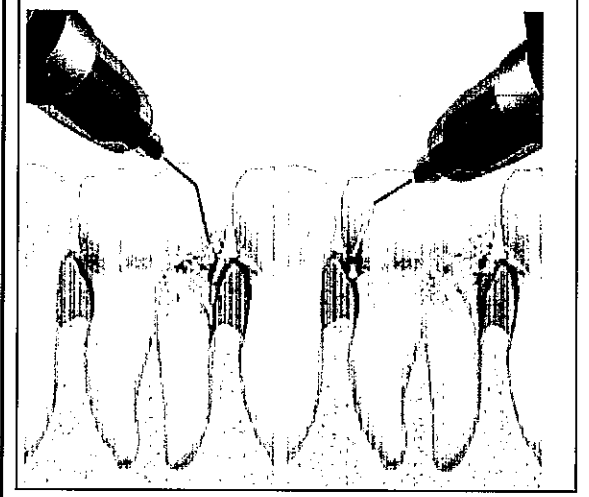
Typically, 1 cartridge (1.7g) or less of Oraqix will be sufficient for one quadrant of the dentition.

When administered, Oraqix should be a liquid. If it has formed a gel, it should be placed in a refrigerator (do not freeze) until it becomes a liquid again.

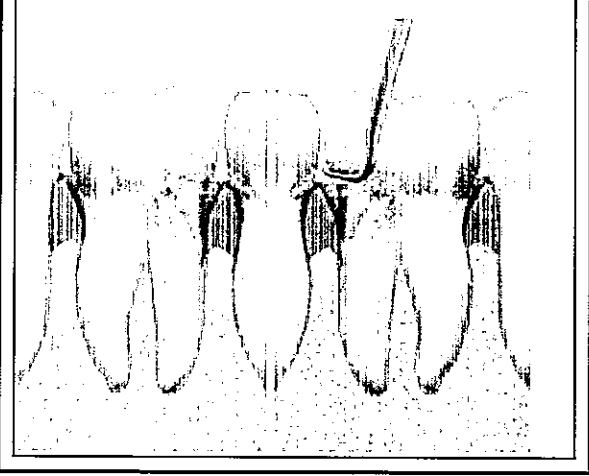
Apply Oraqix on the gingival margin around the selected teeth using the blunt-tipped applicator included in the package.



Wait 30 seconds, then fill the periodontal pockets with Oraqix using the blunt-tipped applicator until the gel becomes visible at the gingival margin.



Wait another 30 seconds before starting treatment.





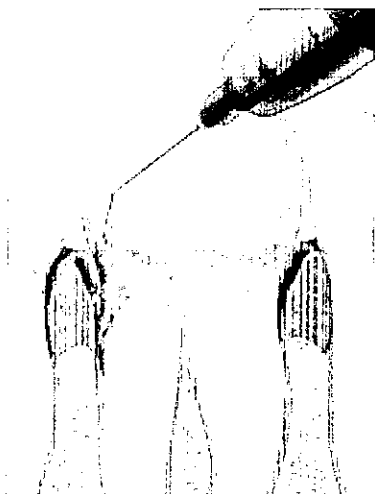
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 Oraqix® Admi
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Needle-free anesthetic.
Don't get stuck without it!

About Oraqix® (lidocaine and prilocaine periodontal gel) 2.5%/2.5%

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It's the first FDA approved needle-free subgingival anesthetic agent providing patients an option in anesthesia for SRP procedures.

Patented thermosetting properties keeps Oraqix® in place during treatment

PRODUCT CHARACTERISTICS

- ◆ Injection-free local anesthetic
- ◆ Needle-free application
- ◆ Proven efficacy for SRP procedures
- ◆ Patented thermosetting property keeps Oraqix in place for effective absorption
- ◆ Local anesthesia specifically confined to the periodontal tissues, without residual numbness of lips and tongue
- ◆ Oraqix can be applied to several quadrants in the mouth in a single visit
- ◆ Oraqix can be reapplied to the same pocket, if a duration of anesthesia longer than 14-31 minutes is required (maximum of five cartridges)
- ◆ **Do not inject Oraqix**

Product Ch.
 Mode of Action & Prc
 Dosage & Ad
 Clir
 Trade Shows & Even



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