

# Fluoride Varnish in a Pediatric Practice

Created by  
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# OMNII | Oral Pharmaceuticals® The Preventive Care Consultants



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# OMNII "Firsts In Dentistry"



OMNII Gel™    PerioMed™    white & brite®    FlossRx™



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## Another OMNII "First" ! CavityShield®



5% Neutral Sodium Fluoride Varnish



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## May 2000 - Cover Story



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## "Off Label" Efficacy

- Tewart & Associates reported that after 2.5 years, the fluoride varnish resulted in a higher percentage of caries reduction than did the 2 % sodium fluoride solution and the 1.23% acidulated phosphate fluoride gel

Source: JADA, MAY, 2000



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## "Off Label" Efficacy

- Numerous randomized clinical trials conducted outside the United States point to the efficacy and safety of fluoride varnishes as a caries-preventive agent

Source: JADA, MAY, 2000



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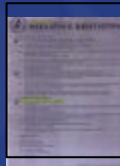
## Other Feature Articles



RDH  
April 2001



Journal of  
Clinical  
Orthodontics  
June 2000



Pediatric  
Dentistry  
November/December 2000



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## March 2001, Washington, D.C.



"The overall preventive effect of professional fluoride gel treatments on caries increments between children treated and children not treated was between 18 and 25 percent. Clinical investigation of the application of fluoride varnish to permanent teeth of children provided preventive effects of between 25 and 50 percent\*."

R. Gary Rozler, D.D.S



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## Worldwide Usage

- Developed in late 1960s and early 1970's
- Numerous studies show efficacy
- Used extensively in Europe and Canada as a primary preventive agent
- 92% of Denmark's municipal preventive programs use Fluoride Varnish exclusively
- As much as 75% reduction in decay\*

\* Goran Kock et. Al. 1975



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## Fluoride Varnishes Available In The U.S.

- Duraphat<sup>®</sup> (Colgate Oral Pharmaceuticals) 5% NaF - 10 ml tube
- Duraflo<sup>®</sup> (Medicom ® Inc.) 5% NaF - 10 ml tube
- Fluor Protector (Ivoclar-Vivadent) 1% Difluorsilane (unit - dose)
- CavityShield<sup>®</sup> (OMNII) 5% NaF (unit -dose)



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## Advantages of Fluoride Varnish

- Neutral taste
- Apply in less than one minute
  - Does not require special equipment or the need for a prophylaxis prior to application
- Safety
- Application in Orthodontics
  - As much as 50% reduction in demineralization <sup>(1)</sup>
- Special applications for handicapped, mentally and medically compromised patients
- Delay caries progression

1. M.A. Todd et al. "Effect of fluoride varnish on demineralization adjacent to orthodontic brackets." American Journal of Orthodontics and Dentofacial Orthopedics (August 1999): 159-167.



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## Neutral Taste

- CavityShield® sets on contact with saliva
- CavityShield® is sweetened with Xylitol



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## Application

- No need for prophylaxis prior to application
- Yellow tint for application control
- "Tooth brush cleaning"
- Applicator brush provided for convenience and cost savings
- Unit-dosed for asepsis control



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## Color



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## Safety Application/Convenience



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## Application Safety



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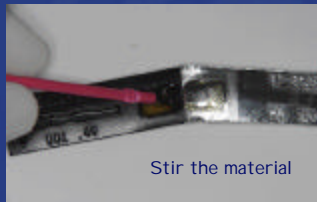
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## Dosage Safety



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## Inherently Inconsistent Dosage Delivery



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## Product Safety

- CavityShield®
  - 1 ml = 50 mg sodium fluoride = 22.6 mg F
  - 22,600 ppm F
- Dosage Applied
  - 0.25 ml for primary dentition
  - 0.40 ml for mixed dentition
  - 0.65 ml for permanent dentition



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## Product Safety



- Following application of varnish on four children, ages 4, 5, 12 and 14: "Peak plasma fluoride concentrations of 3.2 to 6.3 micromolar were found within two hours of treatment... These levels were comparable with those found after brushing with a fluoridated toothpaste (3.63 +/- 0.45  $\mu\text{mol/h}$ ) or after ingesting a 1-mg F tablet (4.47 +/- 0.47  $\mu\text{mol/h}$ ) and were considerably lower than those reported for APF gels (16 to 76  $\mu\text{mol/h}$ )"

If 0.50 ml of varnish is consumed this is 11.3 mg F and is 1/9 the potential toxic dose for a 44lb (20kg) child. Clark et.al.



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## Easy Application



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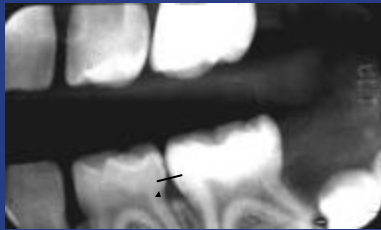
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## Site Specific Application



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## Interproximal Application



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## Orthodontic Application



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## 50% Reduction Demineralized Enamel



J. M. A. Todd et al., "Effect of fluoride varnish on demineralization adjacent to orthodontic brackets," *American Journal of Orthodontics and Dental Orthopedics* (August 1999): 159-167.



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## Conservative Treatment of White Spot Lesions



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## White Lesions Not Visible on X-ray



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## White Spot Treatment



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## Other Current Treatment Modalities

- Severe Early Childhood Caries  
(Arrest progression to time when child will tolerate needed treatment)
- Placement under the flap of partially erupted six or twelve year old molars



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## Glass Ionomer



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## Recharge Fluoride Content



Source: K. Hodsdon, "What about fluorides and sealants," RDH (February 2001): 1618.



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## Fluoride Treatments for the Future



"Nine out of ten patients prefer fluoride varnish."<sup>(1)</sup>

1. C. Terhune, Alty, "Fluoride Varnish, lots of advantages exist for the varnish that is sweeping America," RDH (April 2001): 1819, 94.



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## Care After Treatment

### Directions For Care After Treatment With CavityShield® Fluoride Varnish.

- After the application of CavityShield® you will feel a coating and may notice a difference in color while the varnish remains on your teeth. To obtain the maximum benefit during the 4- 6 hour treatment period, we ask that you take the following care after you leave our office:
- Do not remove CavityShield® by brushing or flossing for at least 4- 6 hours.
- If possible, wait until tomorrow morning to resume normal oral hygiene.
- Eat a soft food diet during the treatment period.
- Avoid hot drinks and products containing alcohol (i.e.: beverages, oral rinses, etc.) during the treatment period.
- A thorough brushing and flossing will easily remove any remaining CavityShield®. Your teeth will return to the same shine and brightness as before the treatment.



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## Cost Per Application\*

- CavityShield® Unit-Dose (0.25 ml - 32 packages) \$0.91
- Duraphat (10 ml tube) \$1.48
- Durafior (10 ml tube) \$1.54

Average cost per application for gel or foam in disposable tray is between \$.55 and \$1.18.

\* Includes cost of brush, if not provided. Retail price comparison (Colgate and Schein) as of 5/2001.



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## OMNII Oral Pharmaceuticals®



800-445-3386



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