


# Procter&Gamble

August 22, 2011

Dear Dental Professional,

This letter provides information regarding updated label instructions on all Fixodent® denture adhesives. Providing safe and effective products for consumers is our number one priority. In support of these efforts, all Fixodent denture adhesive packaging has been updated to provide consumers and professionals with more detailed information on how to use Fixodent denture adhesive. We have also updated the dentureliving.com and dentalcare.com websites. In addition, we are urging denture wearers to consult their dentist or prosthodontist regularly to ensure properly fitting dentures, as poorly fitting dentures may impair health. Frequently this is manifested by oral ulceration and irritation due to aberrant denture movement and the potential for poor nutrition due to reduction in chewing efficiency. Importantly, the patient's quality of life may be impacted because of posturing to hold the denture in place and alterations to speech.

All Fixodent products are safe when used as directed. Patients who are using Fixodent in amounts greater than that directed on the package should be instructed to stop using denture adhesive and be referred to their dentist or prosthodontist to be evaluated for proper denture fit or denture replacement. There is no additional hold benefit by applying more adhesive than directed. Please encourage your patients to schedule regular check-ups to ensure proper fitting dentures. To ensure proper use, please ask your patients to adhere to the labeled directions. An example of these instructions is shown below:

	<b>IMPORTANT:</b> <ul style="list-style-type: none"><li>• <b>DO NOT</b> use more product than shown in diagram (for full dentures, not more than 6 strips or about 3 inches in total length). If product oozes off denture in your mouth you are using too much.</li><li>• <b>DO NOT</b> use product more than once a day. With proper use this tube should last at least 7 to 8 weeks. Write date opened here: ___/___/___</li><li>• <b>DO NOT</b> use excess product for poorly fitting dentures.</li><li>• Consult your dentist regularly to ensure you have properly fitting dentures. Poorly fitting dentures may impair your health.</li></ul>
<ol style="list-style-type: none"><li>1) Clean &amp; Dry Dentures</li><li>2) Apply Adhesive in thin strips as shown</li><li>3) Insert Dentures and hold briefly in place</li></ol>	
<p><b>WARNING:</b> DO NOT use more than directed. Contains zinc. Excessive and prolonged zinc intake is reported to be associated with serious health problems. Consult a doctor if using other products containing zinc.</p> <p>For more support and information about dentures, proper use of adhesives, zinc and other product ingredients, or any other questions or comments, go to <a href="http://www.dentureliving.com">www.dentureliving.com</a> or call 1-800-214-8871.</p> <p><b>INGREDIENTS:</b> CALCIUM/ZINC PVM/MA, MINERAL OIL, PETROLATUM, CELLULOSE GUM, SILICA, RED 27 LAKE.</p> <p><b>Use once a day for All Day Hold. FIXODENT AND FORGET IT!</b></p> <p>Questions? Comments? Call toll-free 1-800-214-8871 Dist. by Procter &amp; Gamble, Cincinnati, OH 45202</p>	

Note that the labeling for Fixodent Food Seal varies slightly since the denture cream is applied in a different manner.

Excessive and prolonged zinc intake from various sources is reported to be associated with copper deficiency, which is a potential risk factor for serious health issues. Recent case reports have suggested that excessive overuse of zinc-containing denture creams may be associated with the development of copper deficiency and the subsequent development of hematological disease and copper deficiency myelopathy. In many of these cases, the reported use of denture cream far exceeds our observed measurements of Fixodent usage. On average, denture wearers use just over 1 gram of Fixodent per day.

Procter & Gamble has conducted extensive scientific research to examine zinc exposure from Fixodent denture adhesive. Clinical and consumer studies were conducted to evaluate Fixodent usage and ingestion. Clinical studies also evaluated the amount of zinc that is absorbed from Fixodent; these studies indicate that very little of the zinc in Fixodent is absorbed when the denture cream is ingested. Based on the information gained from these studies, we calculated zinc exposure from Fixodent denture cream. Our research shows that the amount of zinc an average user absorbs from Fixodent is less than 2 mg per day. Table 1 summarizes zinc exposure as a function of Fixodent usage.

**Table 1: Estimated zinc exposure based on the amount of Fixodent® used per day.**

Percentile	Grams of Fixodent used per day*	Estimated zinc exposure in milligrams per day
1	0.18	0.22
5	0.31	0.37
25	0.63	0.76
50	1.12	1.35
75	1.87	2.26
95	3.08	3.72
99	3.99	4.81

\*"Grams of Fixodent used per day" was determined in a study which included 314 denture wearers. The distribution of denture cream usage is expressed in percentiles. The 50<sup>th</sup> percentile represents average usage. The 1<sup>st</sup> and 99<sup>th</sup> percentiles represent the very low end and very high end of usage, respectively. The majority of the subjects in this study exhibited poorly fitting dentures, as determined by the Kapur method<sup>2</sup>.

<sup>2</sup>Kapur KK. A clinical evaluation of denture adhesives. J Prosthet Dent 1967;18:550-8.

Zinc is an essential mineral that is naturally present in some foods, added to others, and available as a dietary supplement. The recommended daily allowance for zinc is 11 mg per day and 8 mg per day for men and women, respectively. It should also be noted that many multivitamins contain 11 to 15 mg of zinc per tablet.

All Fixodent products undergo rigorous scientific evaluations before marketing. All Fixodent products are manufactured and packaged in accordance with applicable requirements and we also continually monitor the safety of our products once in market.

For additional information, visit [dentalcare.com](http://dentalcare.com) or contact Consumer Relations at 1-800-214-8871.

Regards,



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P&G Oral Health