

19 February 2010

Dear Healthcare Professional

This communication is to alert you of the potential health risk from long-term excessive use of GSK's zinc-containing denture adhesive Polident Extra Hold Denture Adhesive Cream. As patient safety is our foremost concern, as a precautionary measure GSK has voluntarily stopped the manufacture, distribution and advertising of this product.

GSK continuously monitors published scientific literature and the adverse events we receive in relation to all our products. There are a variety of sources of zinc and it is an essential part of a healthy diet. However, in 2009 we received an increased number of adverse event reports. Together with the published literature[#], these suggest that excessive use of these products, typically for several years, may lead to the development of excessive levels of zinc in the body (associated with copper deficiency). The reports describe the development of myeloneuropathy and blood dyscrasias. Neurological symptoms may include sensory disturbance, limb weakness and difficulty walking. These reports are very rare, given that several million people are users of the products.

It is important to note that zinc is not absorbed through the mouth, remaining bound to the adhesive and is only absorbed when swallowed. A small amount of adhesive is swallowed during normal use. This is not considered to be harmful.

Patients who have used Polident Extra Hold Denture Adhesive Cream in accordance with the instructions may continue to do so safely. While the majority of patients do use these products safely, some patients apply more adhesive than directed and use it more than once per day, usually due to ill-fitting dentures. We have advised that these patients should consult their dentist for advice.

We have instructed denture wearers who have used GSK zinc-containing denture adhesive Polident Extra Hold in excess of the product directions for several years or are concerned about their health to discontinue use, consult with their Doctor and use a zinc free alternative. A typical 60g tube of Polident Extra Hold Denture Adhesive Cream should last for at least 5 weeks.

If you have any patients who describe neurological symptoms associated with long-term excessive denture adhesive use, you should refer your patient to their Doctor for assessment. We also ask that you report the case to us (Call 1800 028 533 and tell them that you would like to report an Adverse Event).

If you have any questions, please call 1800 028 533 and Ian Adams, Director Medical & Scientific Affairs or Fiona Dunagan, Medical Affairs Manager will respond to your enquiry.

Regards,



Dr. Howard Marsh
Chief Medical Officer
GlaxoSmithKline Consumer Healthcare

[#] Hedera P, et al. (2009) Myelopolyneuropathy, and pancytopenia due to copper deficiency and high zinc levels of unknown origin II. The denture cream is a primary source of excessive zinc. *Neurotoxicology* 30: 996-999.

Nations SP, et al. (2008) Denture Cream: an unusual source of excess zinc, leading to hypocupremia and neurologic disease. *Neurology* 71:639-643.