

- Consumer health and safety are of the utmost importance to GlaxoSmithKline. Because of this we are issuing a consumer advisory.
- We are alerting consumers, healthcare professionals and other key stakeholders about the potential health risks associated with using excessive amounts of denture adhesives that contain zinc, over the long term.
- Zinc-containing denture adhesives like **Polident Extra Hold Denture Adhesive Cream**, are safe when used as directed. So for the vast majority of people who use the product according to the label, there is no need to do anything.
- People who have been using **Polident Extra Hold Denture Adhesive Cream** in excess over the long term or have a concern about their health should stop using the product and see a doctor.
- In addition to our advisory, and as a precautionary measure to minimise potential risks, we have stopped manufacturing and advertising of zinc-containing **Polident Extra Hold**. **Polident Fresh & Polident Flavour Free** do not contain zinc and will continue to be available on store shelves.

QUESTIONS & ANSWERS

Q1: I have symptoms (i.e. numbness/tingling/weakness), what should I do?

If you are experiencing symptoms please consult a medical professional / your doctor.

Q2: Why has GlaxoSmithKline decided to warn consumers against long term excessive use of zinc-containing denture adhesives?

Consumer health and safety is of utmost importance to GlaxoSmithKline. Because of this, we are issuing an advisory to alert consumers of potential health risks of using excessive amounts of denture adhesives that contain zinc over the long term. Some consumers apply more adhesive than directed and use it more than once per day. Long term, excessive use of zinc-containing denture adhesives has been reported to be associated with certain serious adverse health effects. Therefore, as a precautionary measure to minimize any potential risks to these consumers, GSK has issued this consumer advisory.

Q3: What do you mean by long term excessive use?

Published reports of excessive use have typically described usage of one to two tubes of denture adhesives a week over a period of years. If used as directed a 60g tube of **Polident Extra Hold** should last at least 5 weeks. It is important however that if you are or have been using **Polident Extra Hold** in excess of the instructions that you stop using the product and talk to your doctor about any health concerns you might have.

The instructions printed on the packaging illustrate how to use a small amount to avoid oozing, which can occur if too much product is used. There are picture graphics on the box that show you how to apply **Polident Extra Hold** and approximately how much should be applied to both the upper and lower dentures.

Application of the product should not be required more than once a day. You should not use more than the indicated quantity of **Polident Extra Hold**, or use it more than once per day, to compensate for poorly-fitting dentures. You should consult your dentist regularly to maintain proper-fitting dentures.

Q4: Is too much zinc harmful to me?

There have been reports of excessive use over the long-term of zinc-containing denture adhesive associated with the development of neurological symptoms, which may include

numbness, tingling, or weakness in the limbs, difficulties with walking and balance, and/or the development of blood problems such as anemia.

Q5: I have just seen the product for sale in my local store. Why are you still selling this if it isn't safe?

Polident Extra Hold is safe when used as directed by the product label. GSK has voluntarily stopped the manufacture, distribution and advertising of this product as a precautionary measure. We have done this to minimise potential risks to those consumers who have used excessive amounts of zinc-containing adhesive over the long term.

Q6: What are the specific names of the products being taken off shelf?

As a voluntary precautionary measure to minimise potential risks to consumers, the zinc formulation which will no longer be sold is **Polident Extra Hold**. Zinc-free products, **Polident Fresh & Polident Flavour Free**, will continue to be available on store shelves.

Q7: I do not want to continue using the product and want a refund.

Polident Extra Hold is safe when used as directed by the product label. If you do not want to continue using the product we are able to provide a replacement product that does not contain zinc or we can provide a voucher/refund.

Q8: Does the zinc-free formulation provide the same level of hold?

The zinc-free formulation provides an effective all-day hold for well-fitted dentures.

Q9: What happens if I swallowed some adhesive and/or believe I used the product in excess? What are the symptoms of getting too much zinc?

A small amount of adhesive will be swallowed during normal use which isn't harmful. The product is safe when used as directed.

Ingestion of the adhesive at low levels has not been associated with health concerns. Recent reports regarding zinc-containing denture adhesives suggest that excessive use over an extended period of time may result in a zinc-induced copper deficiency which has been associated with the development of blood problems such as anaemia, and with disorders of the nervous system, termed myeloneuropathy.

Consumers should ensure they are familiar with directions for appropriate use and should consult their physician with questions.

Q10: How much zinc is in your products?

Polident Extra Hold contains 38 mg of zinc per gram (i.e., it is less than 4% zinc by weight). **Polident Fresh** and **Polident Flavour Free** are zinc-free.

Q11: What is myeloneuropathy?

It is a disorder of the nervous system that can be serious, with symptoms that include numbness or weakness in the limbs, poor balance and difficulty walking.

Q12: What are the blood problems associated with long-term excessive use of zinc-containing denture adhesives?

These may include reduced numbers of red blood cells, which is called anaemia, or reduced numbers of certain white blood cells, which can be called leucopenia or neutropenia.

Q13: I can't find my Polident Extra Hold on the shelves. When can I buy it?

GSK has stopped manufacture, distribution and marketing of **Polident Extra Hold**. Zinc free products **Polident Fresh** and **Polident Flavour Free** continue to be available to consumers.

Q14: Should I throw away my zinc-containing Polident Extra Hold product? Is the zinc-containing Polident Extra Hold in my home safe to use?

Consumers in possession of the zinc-containing **Polident Extra Hold** may continue to safely use the product as directed. Consumers should ensure they are familiar with directions for appropriate use. If they prefer, consumers may send the product back to be replaced with a zinc free product **Polident Fresh** or **Polident Flavour Free** or provided a refund/voucher.

