

February 18, 2010

Consumer Advisory

GlaxoSmithKline (GSK) warns about a potential health risk associated with long-term, excessive use of GSK’s zinc-containing denture adhesives Super Poligrip ‘Original’, ‘Ultra Fresh’ and ‘Extra Care’.

This communication is to alert consumers to a potential health risk from long-term excessive use of zinc-containing denture adhesives Super Poligrip ‘Original’, ‘Ultra Fresh’ and ‘Extra Care’.



Original

Ultra Fresh

Extra Care

While zinc is an essential part of the diet, recent publications suggest that an excessive intake of zinc-containing denture adhesives over several years may lead to the development of neurological symptoms and blood problems such as anemia. Neurological symptoms may include numbness, tingling or weakness in the arms and legs and difficulties with walking and balance.

Super Poligrip is safe to use as directed in the product label (see below). The majority of consumers follow these directions. However, some consumers apply more adhesive than directed and use it more than once per day. Therefore, as a precautionary measure to minimize any potential risks to these consumers, GSK has voluntarily stopped the manufacture, distribution and advertising of these products. GSK has discussed this situation with the FDA and no further action is required.

What consumers should do

If you have been using zinc-containing Super Poligrip ‘Original’, ‘Ultra Fresh’ or ‘Extra Care’ for several years in greater amounts than directed on the package or more than once per day, or have concerns about your health, you must:

1. Stop using the product.
2. Talk to your doctor.
3. Use a zinc-free alternative such as Super Poligrip ‘Free,’ Super Poligrip ‘Comfort Seal Strips’, or Super Poligrip ‘Powder’.



Free



Comfort Seal Strips



Powder

Contains no zinc

People with ill-fitting dentures should seek help from their dental care professional, rather than compensate for poorly fitting dentures by using excessive adhesive.

Polident Denture Cleanser tablets contain no zinc and are not affected by this announcement.

GSK will soon be introducing zinc-free versions of Super Poligrip ‘Original’, ‘Ultra Fresh’ and ‘Extra Care’. *Zinc Free Formula* will be clearly shown on the new packaging.

Consumers with questions may call GSK toll free on 1-866-640-1017.

For more information on Super Poligrip and zinc, visit <http://www.poligrip.com>.

Super Poligrip 'Original', 'Ultra Fresh' and 'Extra Care' directions for safe and effective use:

DIRECTIONS: Super Poligrip holds all day. Apply once a day for secure hold. Start with a small amount. Using too much adhesive can cause oozing. If oozing occurs, use less adhesive next time. Do not apply more than once a day. A 2.4 oz tube should last about 8 to 10 weeks. If not, you are using too much adhesive which may be a sign of ill-fitting dentures. See your dentist regularly. Routine dental examinations are part of good oral health and necessary to check the fit of your denture.

APPLYING

1. Clean and dry your dentures.
2. Apply adhesive in two or three short ¼" strips, not too close to denture edges.
3. Rinse mouth before inserting dentures.
4. Press dentures in place, hold firmly, and bite down for a few seconds to secure.
 - To keep tip from clogging, keep cap and nozzle dry.

REMOVING

1. Swish mouth with water.
2. Slowly remove dentures by using a rocking motion.
3. Remove denture adhesive residue from denture and mouth with warm water and a soft brush.
4. Use Polident Denture Cleanser to thoroughly clean your denture.

IMPORTANT PRODUCT INFORMATION:

- This product contains zinc. Talk to your doctor before using this product if you are taking daily zinc supplements.
- Do not use if you have sensitivity to any of the cream ingredients. If discomfort occurs discontinue use.
- Swallowing small amounts of this product, when used as directed, may occur and is not harmful.
- Use only as directed. Using excessive amounts of this product over a prolonged period of time has been reported to result in serious health effects from increased zinc intake.