Eleven cases of oesophageal and gastric obstruction (bezoars) attributed to consumption via gastric tube of a nutrition product in an intensive care unit

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ANSES received eleven reports of severe bezoars likely to be associated with consumption of the enteral (tube-fed) nutrition products Fresubin 2kcal HP Fibre® or Fresubin 2kcal HP® in patients admitted to an intensive care unit. Causality of the product was deemed to be likely or very likely in these cases. ANSES recommends paying close attention to the adverse effects that could occur following administration of any enteral nutrition product, and calls for such effects to be reported to the national nutrivigilance scheme via its website.

In 2023, ANSES published an opinion on nine reports of very severe oesophageal bezoars likely to be associated with consumption of the enteral nutrition products Fresubin 2kcal HP Fibre® or Fresubin 2kcal HP® manufactured by Fresenius-Kabi. These products, marketed in the form of 500ml enteral nutrition bags, are used in hospitals to meet the nutritional needs of undernourished patients. These nine reports were received between 2009 (the year the nutrivigilance scheme was set up) and March 2023.

A bezoar is a compact aggregate of partially digested or undigested material that usually forms in the stomach. It can lead to total obstruction of the digestive tract. Bezoars can occur at any age and are favoured by certain oesophageal diseases or anomalies, gastric emptying disorders, altered gastrointestinal anatomy or certain eating disorders. Depending on the bezoar's characteristics, it may be dissolved using specific chemical solutions or require extraction by endoscopy or even surgery.

NINE CASES OF OBSTRUCTION REPORTED...

The nine cases of oesophageal or gastric bezoars associated with consumption of Fresubin 2kcal HP Fibre® or Fresubin 2kcal HP® involved patients aged between 58 and 76 years (five men and four women), hospitalised in intensive care. The bezoars occurred between three and 28 days after the start of enteral nutrition. Eight of these cases were of severity level 3[1], two of which were life-threatening. The last case resulted in death (severity level 4).

...IN CONNECTION WITH THE USE OF ENTERAL NUTRITION PRODUCTS

The causality of the enteral nutrition products in the occurrence of the bezoars was assessed using the method developed for the nutrivigilance scheme (ANSES 2019).

[1] The scale of severity ranges from Level 1 (low severity) to Level 4 (death).

Causality takes four components into account: the onset time, the outcome after discontinuing the product, whether or not the effect reappears upon reintroduction, and the absence of any other possible explanation for the observed adverse effect. For the enteral nutrition products Fresubin 2kcal HP Fibre® and Fresubin 2kcal HP®, the time to onset of the effect was deemed «compatible». Since the effect abated after discontinuation of the product and after emergency treatment, the progression was described as «suggestive» of an association. Reintroduction was considered «absent» or «inconclusive» because the product was not reintroduced.

The aetiological investigation ruled out the most common causes of bezoars mentioned above, and in all the observed cases, the bezoar was composed of the enteral nutrition product. The Fresubin 2kcal HP Fibre® or Fresubin 2kcal HP® product was therefore deemed very likely responsible, i.e. I4, for the occurrence of the bezoars in eight cases out of nine, and likely responsible, i.e. I3, for one case, on a scale ranging from I0 (excluded) to I4 (very likely).

It should be noted that risk factors may have been involved in the occurrence of the adverse effect under study. The appearance of the bezoars may therefore have been favoured by the illness that led to the patients' admission to intensive care or by the treatments prescribed (morphine, anaesthetics, etc.).

Since publication of the opinion on 11 December 2023, two new cases of bezoar have been reported to the nutrivigilance system, involving these same two products. In both cases, causality was deemed very likely and the severity level was 3 (one was life-threatening).

HAVE SIMILAR CASES BEEN DESCRIBED IN THE SCIENTIFIC LITERATURE?

A literature search on the existence of other cases of bezoar in humans associated with the consumption of enteral nutrition products found no cases associated with the administration of Fresubin 2kcal HP Fibre® or Fresubin 2kcal HP®.

On the other hand, numerous cases of bezoars occurring during enteral nutrition have been published.

They are presented as a potential complication of enteral nutrition and involve risk factors similar to those reported here, in connection with:
- the type and procedures for administration of enteral nutrition: fibre content of the solution, protein content, casein content, positioning of the nasogastric tube, co-administration of medication with enteral nutrition, failure to rinse the tube regularly;
- digestive disorders: digestive stasis, obstruction, motor disorders, dehydration, gastro-oesophageal reflux;
- medication: sucralfate, medicines that slow digestive transit, bulk-forming laxatives, medicines that act on the pH of gastric fluid or enzymatic secretions;
- the context of the stay in the intensive care unit: mechanical ventilation, prolonged recumbency, slowed transit.

ANSES'S WARNINGS AND RECOMMENDATIONS...

Besides the cases involving Fresubin 2kcal HP Fibre® and Fresubin 2kcal HP®, the recurrence of severe cases reported to the nutrivigilance scheme or occurring with other enteral nutrition products led ANSES to:
- alert hospital practitioners to the risk of bezoar formation in patients fed with enteral nutrition products, especially patients with slowed digestive transit;
- recommend that manufacturers of enteral nutrition products conduct studies to identify the conditions under which bezoars form with their products, particularly the interactions with medicines commonly used by enterally-fed patients;
- encourage healthcare professionals to use the dedicated ANSES website[2] to report any adverse effects associated with the use of enteral nutrition products that they observe as part of their professional practice, in order to improve patient safety.

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[2] https://www.nutrivigilance-anses.fr/nutri#!