Hafnia alvei HA4597[®] is the first precision probiotic available as a food supplement

Hafnia alvei HA4597® is commercialized in capsules as a food supplement in France, Portugal, Poland, Italy, Turkey, Croatia, and Germany as of 2023, under the names EnteroSatys®, Satylia® and Satilia®. Here are answers to some of the frequent questions around this product.

Frequently Asked Questions

Q: When should EnteroSatys/ Satylia/ Satilia capsules be taken?

The recommended posology is two capsules per day, as per the protocol of the clinical study: one with breakfast in the morning and one with lunch, to optimize its daylong effects.

Q: Why does EnteroSatys/ Satylia/ Satilia also contain chromium and zinc?

Chromium and zinc were added to the formula to potentiate the action of the product on blood sugar and cholesterol level maintenance. They are also trace elements with authorized European health claims and make it possible to pass on information on blood sugar and macronutrient metabolism to consumers. The sources of zinc and chromium were selected for their qualities: bioavailability, tolerability, and compatibility with *H. alvei*, and the association of these actives is patented.

Q: Does EnteroSatys/ Satylia/ Satilia contain allergens?

Neither the manufacturing process nor the ingredients of the product contain any major allergens (listed in the Reg. No 1169/2011). EnteroSatys/ Satylia/ Satilia contains no gluten, milk proteins nor soy by-products.

Q: Is EnteroSatys/ Satylia/ Satilia manufactured in pharmaceutical GMP-certified facilities?

There are several steps of production, all with recognized quality certifications. The primary and secondary packaging takes place in a pharma GMP-certified facility.

Q: Can people with diabetes take EnteroSatys/ Satylia/ Satilia?

EnteroSatys contains chromium which helps to maintain glycemia levels. This effect must be taken into account for people with Type 1 diabetes, in which case it is recommended to ask one's general practitioner for advice.

Q: Does Hafnia alvei produce or contain histamines?

H. alvei strains have the capacity to produce biogenic amines amongst which we find histamines. However, a high-performance liquid chromatography (HPLC) assay with HA4597 showed a result under the quantifiable limit (<50 ppm), implying that the daily dose of two capsules delivers less than 0.007 mg of histamine. As a comparison, a regular 130g-portion of fish at the safety limit of 50 ppm would deliver 6.5 mg of histamine, and the average consumption of cheese by adults (roughly 50g) would deliver about 18 mg of the compound [1-3]. In conclusion, *H. alvei* HA4597 does not produce histamine in amounts higher than legal safety limits.

However, since some people may be sensitive to histamine (due to diamine oxidase deficiency), they should consider that *Hafnia alvei* HA4597 may produce small quantities of it.

- EFSA Panel on Biological Hazards (BIOHAZ) (2011) Scientific opinion on risk based control of biogenic amine formation in fermented foods. EFSA Journal 9:2393
- Joosten HM, Northolt MD (1989) Detection, growth, and amine-producing capacity of lactobacilli in cheese. Appl Environ Microbiol 55:2356–2359
- French Agency for Food Environmental and Occupational Health & Safety (ANSES) (2009) Etude Individuelle Nationale des Consommations Alimentaires 2 (INCA 2)