

Severe acute hepatitis associated with consumption of a food supplement claimed as being Ayurvedic

ANSES received a report of severe acute hepatitis probably associated with consumption of the SriSri Kanchanara® food supplement; the company placing this product on the market claims that it relates to the practice of Ayurvedic medicine¹. Causality was deemed to be very likely in this case. Given the severity of the adverse effect described, ANSES is bringing this case to the attention of the general public and health professionals [1]. It recommends paying special attention to the adverse effects likely to occur following the consumption of all products containing kanchanara bark and stresses that such effects should be reported to the national nutrivigilance scheme.



As part of its nutrivigilance scheme set up in 2009, ANSES received a report of severe acute hepatitis probably associated with consumption of the food supplement SriSri Kanchanara® marketed by the company Shankara France. This product is made exclusively of the bark of kanchanara, whose scientific name is *Bauhinia variegata*. This plant has traditionally been used in Ayurvedic medicine for its anti-diabetic, antibacterial, antifungal and anti-tumour properties.

The alert

The report involved a 59-year-old woman who had no prior medical history and was not taking any medication. Her alcohol consumption was moderate and occasional.

In late May 2019, she began taking the food supplements SriSri Kanchanara® and SriSri Amruth®. The product SriSri Amruth® was discontinued in late August 2019, i.e. after three months of use.

In mid-October, i.e. after four and a half months of consuming the food supplement SriSri Kanchanara®, she began complaining of fatigue. In late October, the patient observed conjunctival icterus². She stopped taking the food supplement. Four days later, she was hospitalised in a hepatology unit. Clinical

examination found no anomalies, aside from conjunctival icterus. Biological examinations revealed acute cytolytic hepatitis with hepatocellular failure³. A complete aetiological investigation was conducted to identify the cause of this severe acute hepatitis. It ruled out the main infectious diseases, alcoholic liver disease, vascular or biliary disease, Wilson disease⁴, autoimmune disease and a drug-related cause. The results of the liver biopsy were in favour of a toxic disease, but without formally ruling out an infectious disease.

The clinical and biological course was then slow but favourable. The patient returned home in late November 2019, although her liver panel results remained abnormal until February 2020.

Link with the use of these food supplements

The food supplements' causality in the occurrence of the severe acute hepatitis was assessed using the method developed for the nutrivigilance scheme (ANSES, 2019) [2]. Causality takes three criteria into account: the time to onset, the outcome after discontinuing use of the product in question and after its reintroduction where applicable, and other potentially excluded aetiologies.

1. Ayurveda is a natural, traditional medicine system that originated in India more than 5000 years ago.

2. Conjunctival icterus refers to the yellowing of the white of the eye.

3. Hepatocellular failure is defined as a set of clinical and biological signs, due to the impairment of liver cell function, such as asthenia, jaundice, hepatic encephalopathy, skin and endocrine symptoms, haemorrhagic syndromes, and infections.

4. Wilson disease is a genetic disorder characterised by excess copper in the body, especially the liver.

For the SriSri Kanchanara® food supplement, the time to onset of the effect was considered “compatible”. The adverse effects regressed when the SriSri Kanchanara® product was no longer consumed and the slow regression kinetics were due to the severity of the hepatic disorders. The outcome was therefore described as “suggestive”. The aetiological investigation ruled out the most frequent causes of acute hepatitis. The SriSri Kanchanara® product was therefore deemed **very likely** responsible for the occurrence of this severe acute hepatitis, i.e. **I4**, on a scale ranging from I0 = excluded to I4 = very likely.

This same expert assessment was undertaken for the SriSri Amruth® food supplement. The time to onset of the effect was deemed “incompatible”, as the product had been discontinued around two months before the onset of the first clinical signs. The responsibility of the product SriSri Amruth® in the occurrence of this severe acute hepatitis was therefore excluded (i.e. I0).

Have similar cases been described in the scientific literature?

The literature search focused on the potential hepatotoxicity to humans of the ingredient in the SriSri Kanchanara® food supplement, i.e. kanchanara (*Bauhinia variegata*) bark. Only one clinical case of liver damage has been published involving the consumption of kanchanara. It describes the case of a 44-year-old woman who developed jaundice, discoloured stools and dark urine after six months of consuming three plant-based products/homoeopathic medications (*Kanchnar guggulu*, *Punarnava Mandur* and a third unidentified product). Following an aetiological investigation, toxic hepatitis was diagnosed. The outcome was favourable upon discontinuation of the three products. As several multi-ingredient products were consumed and one could not be identified, the occurrence of this hepatitis reported in the literature cannot be exclusively attributed to kanchanara. No other cases have been published and in particular, there have been no published cases where kanchanara was the sole plant in question.

Have similar cases been reported to the nutrivigilance scheme?

Another case of liver damage involving a product named

“Kanchanara” was reported to the nutrivigilance scheme. In this case, two other food supplements had been consumed simultaneously (*Curcuma longa* and *Bringaraj*). Since the ingredients in these three products could not be precisely identified, no causality analysis could be conducted for this case.

Conclusion and recommendations

For the case reported here, the causality of the SriSri Kanchanara® food supplement in the occurrence of severe acute hepatitis was deemed very likely. The current data are not sufficient to formally conclude as to the hepatotoxic nature of the kanchanara plant, traditionally used in Ayurvedic medicine. However, in view of the various identified signals and growing public interest in these products, special attention should be paid to the adverse effects likely to occur following consumption of this plant.

ANSES reiterates its usual recommendations concerning food supplements. It recommends that:

- Consumers should:
 - notify a healthcare professional of any adverse effect occurring after consumption of a food supplement;
 - comply with the conditions of use specified by the manufacturer;
 - avoid taking food supplements on a multiple, prolonged or repeated basis throughout the year without having sought the advice of a healthcare professional (doctor, pharmacist, etc.);
 - be wary of the therapeutic properties attributed to food supplements;
 - exercise great caution regarding the purchase of products via alternative channels (Internet, gyms, etc.) and without personalised advice from a healthcare professional.
- Healthcare professionals should communicate cases of adverse effects they suspect of being associated with the consumption of food supplements and report these to the nutrivigilance scheme.

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Where should reports be sent?

Adverse effects can be reported on the [Adverse Health Event Reporting Portal](#) of the Ministry of Social Affairs and Health or directly by completing [the online reporting form](#).

References

- [1] [ANSES Opinion on a case of severe acute hepatitis associated with consumption of the SriSri Kanchanara® food supplement](#)
- [2] [ANSES Opinion on updating the method for determining causality in reports of adverse effects in nutrivigilance](#)