

Data published in the literature

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This is a discussion paper. It does not reflect the views of the Committee. It should not be cited.

54. The clinical cases reported in the literature up to October 2024 were mainly hepatic effects (n = 35). Psychiatric (n = 8), cardiovascular (n = 3), digestive (n = 3), muscular (n = 2) and metabolic (n = 2) disorders were the subject of several publications. Authors of these publications utilised *G. cambogia* and did not further allow for accurate scientific identification.

Hepatotoxicity

55. Thirty-six cases of liver damage have been published, observations by ANSES were discussed in their Opinion.

56. In brief, hepatitis of the cytolytic type were observed (86%), followed by cholestatic hepatitis (8%) and mixed hepatitis (6%). Grade 2 hepatitis was observed with elevation of transaminases (greater than 3 times the normal range) in the majority of cases; however, some were life-threatening (n=6), or even fatal (n=1). 60% of the reported cases involved women aged 37 years on average (35 years as the median; 19 - 64 years age range).

57. In 20 of the 36 publications, co-morbidities were reported, including hypertension, heart or kidney failure, diabetes, haemochromatosis, allergy, hypothyroidism, adenoma, chronic pain, dyslipidaemia, or hepatic steatosis. Authors of the publications identified risk factors for certain pathologies, including high BMI, hypocaloric diets, intense physical activity, a history of hepatitis, rapid and significant weight loss, alcohol use, and smoking.

58. In 29 of the 36 publications, the composition of the food supplements was of sufficient detail to identify other ingredients. Within these 29, 24 involved dietary supplements containing *G. cambogia* in combination with other hepatotoxic ingredients: caffeine, piperine or chromium. Most cases involving multi-ingredient products have been reported in the United States in people who have consumed products from the Hydroxycut® range. The composition of Hydroxycut® products in reported cases is often vague or entirely unknown.

59. Besides these occasional published cases, research teams have also analysed database records of liver damage linked to toxic drugs or plant-based products.

60. As part of the US Drug Induced Liver Injury Network (DILIN), Vuppalanchi *et al.*, (2022) published their analysis of the 22 cases related to *G. cambogia* hepatotoxicity. Five of the twenty-two cases could be attributed to *G.*

ambogia alone, in combination with green tea (n=16/22) or *Withania somnifera* [ashwagandha] (n=1/22). Statistical tests comparing control groups—patients with liver injury linked to green tea supplements without *G. cambogia* (n=57) or to other herbal supplements (n=103) showed that liver damage caused by *G. cambogia* and green tea was clinically indistinguishable. Patients who developed liver damage from dietary supplements containing *G. cambogia* showed a significantly higher frequency of the HLA-B*35:01 allele compared to those whose liver injuries were linked to other herbal supplements or conventional medications. The authors concluded that this association suggested a mode of action that is mediated by the immune system.

61. Bessone *et al.*, (2022) analysed the Latin America-Drug Induced Liver Injury (LATINDILI) database, they found that out of 367 cases, 8% were attributed to herbal food supplements. *Camellia sinensis* [green tea], Herbalife® products, and *G. cambogia*—mostly used for weight loss—were the most frequently identified as causes.

Psychiatric disorders

62. Four of the eight cases involved people with a history of psychiatric disorders. This was identified to be a potential risk factor, although adverse reactions have also occurred in individuals without any known psychiatric history.

Cardiovascular disorders

63. Two cases of cardiomyopathy and one case of giant cell myocarditis have been reported in the literature.

64. The Plants WG and the Human Nutrition Expert Committee noted that both cases of cardiomyopathy involved women with no prior medical history. The clinical observations were deemed to be severe; one led to cardiac arrest, and the other caused high blood pressure with cardiac dysfunction, requiring ongoing cardiology follow-up.

Digestive disorders

65. The Plants WG and Human Nutrition Expert Committee noted that acute lithiasis pancreatitis often occurs in cases of obesity and diabetes. These three cases of pancreatitis occurred in people with diabetes and hypertension. Two of the three cases involved a history of obesity and chronic hepatitis C.

Muscle disorders

66. Two cases of rhabdomyolysis following consumption of Hydroxycut® have been reported in the literature. During periods of consumption (prior to 2009 [when the US FDA requested the withdrawal of *G. cambogia* from the product – see paragraph 36]), ephedra, caffeine, chromium, *G. cambogia* and *Gymnema sylvestre* [gymnema] were part of the composition of Hydroxycut®. These cases involved women who were either overweight or had recently increased their physical activity.

Metabolic disorders

67. Roche *et al.*, (2014) reported a case of hypoglycaemia (blood glucose at 33 mg/dl) leading to syncope in a 67-year-old woman. The woman had been taking the following medications: venlafaxine, lisinopril-hydrochlorothiazide and alprazolam. She had started taking a dietary supplement containing *G. cambogia* two days before the onset of hypoglycaemia. The symptoms disappeared after administration of glucose. The author suspected *G. cambogia* because of the temporality of the events and the nonrecurrence of similar events following discontinuation of the product.

68. Bystrak *et al.*, (2017) reported a case involving digestive complications in a 56-year-old consumer with diabetes, the patient developed diabetic ketoacidosis. The authors suggested *G. cambogia* may have triggered ketosis by increasing ketone body production.

Other types of disorders

69. A 35-year-old woman with no known medical history or medication use reported an ocular disorder unilateral vision loss and eye pain after taking over 1,500 mg of HCA daily from *G. cambogia* extract for one week (Cho *et al.*, 2019). These ocular complications resolved after the extract was discontinued and treatment with topical and oral steroids was initiated.

70. Other publications of adverse reactions suspected to be related to consumption of *G. cambogia* provided little descriptive information on the product label and in general e.g. dose, exposure duration, presence of other hepatotoxic ingredients. Two studies (Sikka *et al.*, 2016; Graf *et al.*, 2020) reported cases of thrombocytopenia in connection with taking dietary supplements containing *G. cambogia*. Li and Bordelon (2011) reported a case of nephropathy occurring in a

51-year-old woman with no previous medical history in association with one month's consumption of a dietary supplement containing *G. cambogia*.