Update liver toxicity of Ashwagandha-containing products

Introduction

Withania somnifera (L.) Dunai, commonly known as "Ashwagandha" or "Indian ginseng" is a therapeutic plant, widely cultivated in India and throughout the Middle East and is found in eastern Africa. Ashwagandha belongs to the genus *Withania* and family *Solanaceae* [1, 2]. The principal bioactive compounds of *Withania somnifera* are withanolides, which are steroidal lactone triterpenoids. More than 40 withanolides, approximately 12 alkaloids and several sitoindosides have been isolated and identified from *Withania somnifera* [1].

Withania somnifera is claimed to have various biological actions such as anticancer, anti-inflammatory, antidiabetic, antimicrobial, anti-arthritic, anti-stress/adaptogenic, neuroprotective, cardioprotective, hepato-protective and immunomodulatory properties. It has been and is regularly used in traditional medicine, alone or in combination with other plants. For the treatment of various illnesses, as an adaptogen, diuretic and sedative [1, 2]. Its efficacy has not been consistently shown in rigorously controlled prospective studies. But having been used in Ayurvedic medicine for centuries, it is currently becoming popular as an herbal product in Western countries. Especially because of its assumed adaptogenic properties. Meaning that it helps the body to cope with stress and anxiety while maintaining an overall wellbeing [3].

Information about adverse reactions is scarce, since limited clinical trials are available. Somnolence, diarrhoea and abdominal pain have been more commonly reported with ashwagandha compared to placebo[1]. In clinical trials, there have been no reports of serum liver enzyme elevations occurring during therapy and no mention of serious adverse events or hepatotoxicity[3]. Recently, however, several cases of clinically apparent liver injury have been reported in patients taking commercial herbal products that are labelled as containing Ashwagandha[3].

Products containing Ashwagandha are available in the Netherlands as dietary supplements (thus without the pre-marketing authorization required for medicines).

In September 2023 the Netherlands Pharmacovigilance Centre Lareb reported about liver toxicity associated with Ashwagandha containing products. This is an update with additional reports received up to June 2025.

Reports

Since September 2023 Lareb has received eight additional reports on liver toxicity associated with products containing Ashwagandha (Table 1 cases 5-12)). Listed ingredients of the suspected products are shown in Table 2.

Table 1. Reports on liver toxicity associated with products containing Ashwagandha

No	ID, sex, age, primary source	Suspect product	Dosage	Indication	Concomitant medication	Reported ADRs	Latency after start	Action taken	Outcome
1	NL-LRB-00861365, female, 20-30 years, Consumer or other non-health professional	Stress-Less Viteezy	1 tablet / 1 Day	Stress	Prenatal Viteezy, Energy Assistant Viteezy	Hepatitis	5 Months	Drug Withdrawn	Recovering

2	NL-LRB-00306040, male, 30-40 years, Physician	Kudzu Optimum Exendo, NMDA Relief Exendo, Mentalis Stress Trenker	1 capsule / 1 Day	Stress		Hepatitis	3 weeks 3 months 3 months	Unknown	Recovering
3	NL-LRB-00903093, female, 60-70 years, Physician	Biologische Ashwagandha Poeder Hanoju	0.5 teaspoon / 1 Day	Cognitive disorder	Vitamin C, Vitamin B complex	Liver function test abnormal, Icterus, Transaminitis, Cholestasis	10 Months 10 Months 10 Months 10 Months	Drug Withdrawn	Recovering
4	NL-LRB-00899249, female, 30-40 Years, Physician	Ashwagandha Ksm 66 Holland & Barrett	1 capsule / 1 Day	Panic reaction Stress	Lorazepam, Macrogol Drink	Hepatic function abnormal	5 Months	Drug Withdrawn	Recovering
5	NL-LRB-01020172, female, 50-60 Years, Physician	Ashwagandha (product not further specified)	1 dosage form / 1 Day	Stress		Hepatitis cholestatic	22 Months	Drug Withdrawn	Recovered
6	NL-LRB-01000314, male, 50-60 Years, Physician	Ashwagandha Ksm 66 Holland & Barrett	3 capsules / 1 Day	Supplementation therapy	Dolutegravir Tablet 50Mg, Emtricitabine/Tenofovir alafenamide Tablet 200/ 25Mg	Hepatitis	2 Months	Drug Withdrawn	Recovered
7	NL-LRB-00957830, female, 50-60 Years, Consumer or other non health professional	Ashwagandha Ksm 66 Holland & Barrett		Stress management Menopausal symptoms		Liver damage, fatty liver disease	unknown	Drug Withdrawn	Unknown
8	NL-LRB-00947210, female, 50-60 Years, Consumer or other non health professional	Ashwagandha (product not further specified)	1 dosage form / 1 Day	General physical condition Insomnia		Hepatic enzymes increased, TSH increased	6 Weeks 6 weeks	Drug Withdrawn	Recovering Recovering
9	NL-LRB-00931545, female, age unknown, Consumer or other non health professional	Biologische Ashwagandha Poeder Hanoju	Half a teaspoon/ 1 Day	Product used for unknown indication		Hepatitis	1 Year	Unknown	Not Recovered
10	NL-LRB-01017393, male, 30-40 years, Consumer or other non health professional	Testo Charge Zapply	1 dosage form / 8 Hours	Testosterone	Magnesium Orangefit, Probiotica Orangefit	Hepatic enzymes increased	2 Months	Drug Withdrawn	Not Recovered
11	NL-LRB-01014084, male, 70-80 years, Consumer or other non health professional	Mentaserin Flinndal	/	Memory impairment	Metoprolol, ezetimibe, losartan, amlodipine, omeprazol, coumarin	Hepatitis acute	2 Months	Drug Withdrawn	Recovered
12	NL-LRB-01003585, female, 50-60 years, Physician	Ayurmenopause Ojas	1 dosage form / 12 Hours	Menopausal symptoms	Rosuvastatine Tablet 20Mg,	General malaise, Abdominal	6 Months ---------- --	Drug Withdrawn	Not Recovered, Not

					Macrogol Poeder V Drank 10G , Calciumcarbonaat Bruistablet 1,25G (500Mg Ca) , Eclipta Alba , Shilajit Extract	pain , Jaundice	6 Months ---------- -- 6 Months		Recovered , Not Recovered

NL-LRB-00861365: Five months after start of Stress-Less Viteezy the patient experienced a hepatitis with jaundice, abdominal pain, nausea, vomiting, inflammation of the skin, myalgia, earache, fatigue and fever. Patient was admitted to the Emergency department where a liver biopsy, echo and blood test were performed (results are unknown). Patient was treated with pain medication, medication to treat her nausea and corticosteroid cream. At the moment of reporting she is recovering. The suspected product contains multiple herbs and other ingredients, however, only the ingredient Ashwagandha is mentioned as a probable cause of clinically apparent liver injury in LiverTox[3]. Comedication also contained multiple herbs and vitamins, but these herbs and vitamins are not mentioned in LiverTox as a cause of liver injury[3]. Development of liver function test over time were not reported. Serological tests for hepatitis A,B,C, CMV, HSV, EBV were not reported. The RUCAM (Roussel Uclaf Causality Assessment Method) was used to asses causality of drug induced liver injury[4]. For this case a RUCAM causality assessment is unreliable because of missing detailed information for several key elements (no specification of liver enzyme levels, course of liver enzymes and exclusion of other causes of liver injury).

NL-LRB-00306040: The patient was hospitalised and received conservative treatment. Liver function tests showed aspartate aminotransferase (ASAT) 2600 U/L, alanine aminotransferase (ALAT) 4100 U/L, alkaline phosphatase (AP) 288 U/L and total bilirubin 150 umol/L. The patient had a mixed hepatic injury. Of the three suspect products only NMDA Relief Exendo and Mentalis Stress Trenker contain ingredients mentioned to cause liver injury in LiverTox. NMDA Relief Exendo contains *Scutellaria baicalensis* (very likely but rare cause of clinically apparent liver injury according to LiverTox)[3]. Mentalis Stress Trenker contains Ashwagandha (probable cause of clinically apparent liver injury according to LiverTox)[3]. It is not reported if the patient suffered from abdominal pain, fever, jaundice or itching. Development of liver function test over time were not reported. Serological tests for hepatitis A,B,C, cytomegalovirus (CMV), herpes simplex virus (HSV) or Epstein-Barr virus (EBV) were not reported. For this case a RUCAM causality assessment is unreliable because of missing detailed information for several key elements (course of liver enzymes and exclusion of other causes of liver injury).

NL-LRB-00903093: Liver function tests one year after start of using Ashwagandha powder showed ASAT 1138 U/L, ALAT 1278 U/L, AP 157 U/L and total bilirubin 176 umol/L. Another symptom reported was fatigue. Five weeks earlier the patient had an increased INR. The patient also used vitamin C and vitamin B complex, no other comedication was used. The patient had no history of liver function disorder and did not use alcohol. Tests excluded hepatitis A, B, C and E. HSV was not tested. Auto-immune hepatitis was excluded. Patient had had an EBV infection in the past. The initial step in the RUCAM assessment is to define whether the hepatic injury is “hepatocellular”, “mixed”, or “cholestatic.” These terms refer to the pattern of serum enzyme elevations at disease onset and are defined by calculation of the “R ratio”. This case had an R value of 23, which results in a

“hepatocellular” hepatic injury. The RUCAM score was 6 (‘probable‘ that the drug is a cause of the liver injury).

NL-LRB-00899249: The patient was hospitalised for observation of her liver function. Liver function test were two weeks after start slightly raised, but increased further in the months thereafter. Five months after start liver function test showed ASAT 221 U/L, ALAT 489 U/L, AP 366 U/L and total bilirubin 4 umol/L (Reference values ASAT 31 U/L, ALAT 34 U/L, AP 98 U/L and total bilirubin 17 umol/L). The patient reported not to use any alcohol. She reported to use lorazepam as comedication. The product information of lorazepam mentions abnormal liver function tests as adverse drug reaction[5]. Tests excluded hepatitis C. Patient was vaccinated for hepatitis B and had had an infection of CMV and EBV in the past. Abdominal CT and abdominal ultrasound were without abnormalities. This case had an R value of 2.4, which results in a “mixed” hepatic injury. The RUCAM score was 2 (‘unlikely‘ that the drug is a cause of the liver injury). However, not all information was available resulting in less points that could be added.

NL-LRB-01020172: Cholestatic hepatitis was confirmed by imaging and liver biopsy. Patient was treated with ursodeoxycholic acid. No further information was available. For this case a RUCAM causality assessment is unreliable because of missing detailed information for several key elements (no specification of liver enzyme levels, course of liver enzymes and exclusion of other causes of liver injury).

NL-LRB-01000314: The patient did not have any health complaints. Routine screening showed ALAT 1543 U/L 1,5 months after start of Ashwagandha. The patient reported not to use alcohol. The patient reported to use dolutegravir as comedication. The product information of dolutegravir mentions abnormal liver function tests and hepatitis as adverse drug reactions[6]. One week after withdrawal of Ashwagandha liver function tests showed ASAT 55 U/L, ALAT 102 U/L, AP 192 U/L and total bilirubin 38 umol/L. These values further declined the following month. Imaging of the liver and blood test showed no evidence of another cause such as viral or autoimmune hepatitis. For this case a RUCAM causality assessment could not be calculated due to missing information about AP.

NL-LRB-00957830: By chance it was discovered that the patient had fatty liver disease. Patient had no health complaints. Imaging revealed fatty liver disease. Blood tests showed mild liver damage. Liver function test values are unknown. Patient had used Ashwagandha for one year. For this case a RUCAM causality assessment is unreliable because of missing detailed information for several key elements (no specification of liver enzyme levels, course of liver enzymes and exclusion of other causes of liver injury).

NL-LRB-00947210: The patient reported increased hepatic enzymes, but no further information about blood tests was provided. Patient was treated with unspecified pain medication. For this case a RUCAM causality assessment is unreliable because of missing detailed information for several key elements (no specification of liver enzyme levels, course of liver enzymes and exclusion of other causes of liver injury).

NL-LRB-00931545: The patient reported hepatitis, but no further information about blood tests was provided. For this case a RUCAM causality assessment is unreliable because of missing detailed information for several key elements (no specification of liver enzyme levels, course of liver enzymes and exclusion of other causes of liver injury).

NL-LRB-01017393: Two months after start ALAT was 89 U/L. Data for ASAT and AP were not provided. For this case a RUCAM causality assessment is unreliable because of missing detailed information for

several key elements (no specification of liver enzyme levels, course of liver enzymes and exclusion of other causes of liver injury).

NL-LRB-01014084: Two weeks after start of complaints liver function test showed ASAT 28 U/L, ALAT 69 U/L, AP 140 U/L and total bilirubin 12 umol/L. The patient reported not to misuse any alcohol. Tests excluded hepatitis A, C and CMV infection. Patient was vaccinated for hepatitis B. Patient had had an infection of EBV and probably hepatitis E in the past. The RUCAM score was 9 ('highly probable' that the drug is a cause of the liver injury).

NL-LRB-01003585: Six months after start of Ayurmenopause Ojas liver function test showed ASAT 1233 U/L, ALAT 1551 U/L, AP 160 U/L and total bilirubin 73 umol/L. For this case a RUCAM causality assessment is unreliable because of missing detailed information for several key elements (no course of liver enzymes and exclusion of other causes of liver injury).

Table 2. Product information available on the product websites of the Ashwagandha-containing products in the reports

Product	**Ingredients per dose form**	**Recommended daily dose**
Stress-Less Viteezy	Melissa officinalis (4:1 extract) 30 mg; Ashwagandha (2:1 extract) 75 mg; Rhodiola rosea (2:1 extract) 100 mg; Maca (4:1 extract) 10 mg; Panax ginseng (1:1 extract) 100 mg; Magnesium (taurate) 18 mg; Zinc (bisglycinate) 25 µg; Vitamin B12 (adenosylcobalamin) 500 µg; Vitamin B12 (methylcobalamin) 500 µg; Taurine 50 mg	1 tablet per day
Mentalis stress Trenker	Ashwagandha extract (KSM-66 300 mg; 100% inactivated Saccharomyces Cerevisiae 100 mg; Magnesiumoxide 75 mg; vitamin B3 8 mg; superoxide dismutase (SOD 15000 IU/g) (Cucumis melo L.) 5 mg; vitamin B5 3 mg; vitamin B6 0.7 mg; vitamin B2 0.7 mg; vitamin B1 0.55 mg; vitamin B9 100 µg; vitamin B8 25 µg; vitamin B12 1,25 µg	1-2 capsules per day
Biologische Ashwagandha poeder Hanoju	Ashwagandha powder	3 grams per day
Ashwagandha KSM 66 Holland & Barrett	Ashwagandha extract KSM-66® (root) 500 mg; cellulose; zinc oxide	1 capsule per day

Testo Charge Zapply	vitamin D3 6,6 ug; vitamin B6 1,7 mg; zinc 3,33 mg; magnesium bisglycinate 66,8 mg; copper bisglycinate 0,17 mg; Shilajit extract 133,3 mg; Black maca extract 66,7 mg; Cordyceps extract 33,3 mg; Ashwagandha KSM-66 66,7 mg; Boron 2,5 mg; Milk thistle extract 33,3 mg	3 capsules per day
Mentaserin Flinndal	Bacopin® (Bacopa monnieri) 125 mg Cognizin® citicoline 125 mg Sensoril® Ashwagandha rootextract 125 mg NeuroPeak® 70 SUN fosfatidylserine 50 mg vitamin B1 0,55 mg vitamin B3 16 mg vitamin B5 9 mg vitamin B6 2,5 mg Quatrefolic® Active folic acid 100 µg vitamin B12 2,5 µg	2 capsules per day
Ayurmenopause Ojas	Withania somnifera (L.) Dunal 150 mg calciumcarbonate E170 60 mg Acacia 45 mg Centella asiatica (L.) urb 45 mg Emblica officinalis 45 mg Glycyrrhiza glabra L 25 mg Nardostachys grandiflora DC 25 mg Aloe vera (L.) Burm. f 25 mg Crocus sativus L 20 mg	2 capsules per day

Other sources of information

Literature

Various cases of liver injury that was possibly Ashwagandha-related have been reported in the literature. The liver enzyme abnormalities in most patients self-resolved within one to five months after withdrawal [7-18]. Björnsson et al. has published a series of five cases, with two from the USA and three from Iceland suspecting Ashwagandha-induced liver injury. The described five patients (three males, two females) had a mean age of 43 years, and developed jaundice after a latency ranging from 2 to 12 weeks. Liver injury was cholestatic or mixed. Other causes for liver injury were excluded [7]. Ireland et al. reported another case of a 39-year old woman developing acute hepatitis, classified as hepatocellular, following the use of Ashwagandha [9]. In addition Weber et al. reported a case of a 40-year-old man with acute liver injury after using Ashwaganda. The type of liver injury was not further specified [18]. Toth et al. reported a case of Ashwagandha-induced acute liver injury, with jaundice two weeks after start of Ashwagandha [17]. The liver biopsy revealed prominent hepatocellular and canalicular cholestasis as well as spotty hepatocellular necrosis. Other causes for liver injury were excluded. Suryawanshi et al. reported a case of a 41-year-old female that developed a hepatocellular pattern of acute liver failure and required liver transplantation after two months use of Ashwagandha

[16]. Philips et al. reported a case series of Ashwagandha-induced liver injury from India. They describe eight patients with liver injury truly attributable to a single-ingredient formulation among 23 patients with liver injury from consuming Ashwagandha-based supplements. Cholestatic hepatitis was the commonest presentation[19].

The Netherlands National Institute for Public Health and the Environment (RIVM) advises against consuming dietary supplements that contain Ashwagandha. Physicians in the Netherlands and other countries have reported cases of poisoning among people who had consumed these supplements. This included harmful effects in the liver. The effects can be serious and may occur even when people use the product as instructed on the packaging [20].

Other databases

On June 23rd 2025 the WHO database (Vigibase) contains 25 reports of Hepatobiliary disorders (SOC) and/or Hepatobiliary investigations (HLGT) of the Investigations (SOC) associated with *Withania somnifera* (Table 3). One report can contain multiple reactions.

Table 3. Reactions of liver toxicity associated with *Withania somnifera* in Vigibase

Active ingredient	Reaction (PT)	Number of reports
Withania somnifera	Jaundice	8
Withania somnifera	Alanine aminotransferase increased	4
Withania somnifera	Cholestasis	3
Withania somnifera	Acute hepatic failure	3
Withania somnifera	Liver injury	2
Withania somnifera	Blood bilirubin increased	2
Withania somnifera	Liver function test abnormal	2
Withania somnifera	Hepatitis cholestatic	2
Withania somnifera	Hepatic enzyme increased	2
Withania somnifera	Hepatitis	2
Withania somnifera	Hepatic function abnormal	2
Withania somnifera	Aspartate aminotransferase increased	2
Withania somnifera	Jaundice cholestatic	1
Withania somnifera	Hypertransaminasaemia	1

Withania somnifera	Hepatocellular injury	1
Withania somnifera	Drug-induced liver injury	1
Withania somnifera	Hyperbilirubinaemia	1
Withania somnifera	Hepatic failure	1

Mechanism

The cause of hepatotoxicity from products containing Ashwagandha is unclear, but may be caused by withanolides forming irreversible adducts with hepatocellular DNA [12]. Lubarska et al. suggest that Ashwagandha consumed in excess causes a reduction in GSH levels in cells, which translates into cytotoxicity and may explain the cause of liver damage [10].

Discussion and conclusion

Up to June 2025, Lareb has received twelve reports of liver toxicity associated with the use of Ashwagandha-containing products. In seven reports the suspect product contained only Ashwagandha. In five reports multiple ingredients were present. In some of these reports other herbs associated with liver toxicity such as *Scutellaria baicalensis, Centella asiatica* or *Aloe vera* had also been used. Time to onset varied from six weeks to one year. The latency of drug-induced liver injury is typically between five days and three months after starting a medicine. Measurement of time to onset, however, may be difficult. The latency is usually measured from the time of starting the suspect product to the time of onset of jaundice, dark urine or detection of an elevation in serum bilirubin; but in other situations latency is measured from the time of starting the suspect product to the time of the first symptom, which might be fatigue, weakness, nausea, poor appetite, abdominal pain, fever, rash or itching[21].

Ten patients reported to have withdrawn the Ashwagandha-containing product and of two patients the action taken is unknown. Eight patients were recovering/had recovered at the time of reporting. Three patients had not recovered yet at the time of reporting, while of another patient this is unknown. Typically, improvement of drug-induced liver injury starts within a week or two after stopping therapy, and the injury resolves completely within two to three months[21].

In the determination of the RUCAM score, age ≥ 55 years is a risk factor for liver injury[4]. Seven of the twelve patients in the reports received by Lareb were younger.

Several cases of clinically apparent liver injury have been reported in the literature of patients taking herbal products that are labelled as containing Ashwagandha[7, 9, 16-19].

It is important to note that herbal preparations can be mixtures of herbs. Other herbs present in these products could also have contributed to the observed liver toxicity. Furthermore, herbal preparations can contain ingredients that are not labelled or contaminants. Therefore, it cannot be totally ruled out that reported cases are due to unlabelled ingredients or a contaminant. Dietary supplements have a less stringent regulatory framework compared to medicines. While manufacturers are responsible for ensuring safety and accurate labelling, there is no pre-approval for safety or effectiveness for dietary supplements before they enter the market. This can raise concerns about quality compared to medicines.

Herbal products are generally considered safe by consumers, but can have serious adverse reactions. Although rare, it is important to raise awareness of the potential risk of liver toxicity of Ashwagandha-containing products.

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