

Severe Liver Injury Associated with the Use of Unregulated Herbal Products: A Case Report and Literature Review

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ABSTRACT

The use of phytotherapeutic products and herbal supplements has increased, partly because many people believe “natural” products are harmless. However, their consumption may cause herb-induced liver injury (HILI), particularly when they are used without medical supervision or marketed as falsified products. We report the case of an 85-year-old man who presented with right upper quadrant pain and jaundice and was found to have a hepatocellular pattern of liver injury (R-value 11.3). Further history revealed the use of six phytotherapeutic products for six months, including Redumex, whose registration could not be verified, and Vitacerebrina Francesa, lot VTMA513, which INVIMA identified as a fraudulently marketed product bearing a false sanitary registration. Causality was classified as possible using RUCAM (score: 5), whereas severity was classified as DILIN grade 4. Following withdrawal of the products, the patient showed clinical improvement and a progressive decline in aminotransferase and alkaline phosphatase levels, allowing hospital discharge with instructions to avoid re-exposure. This case highlights the importance of systematically investigating herbal product use and strengthening pharmacovigilance and regulatory control of falsified products.

Keywords: Chemical and Drug-Induced Liver Injury; Plant Preparations; Dietary Supplements; Pharmacovigilance; Counterfeit Drugs.

Lesión hepática grave asociada al consumo de productos fitoterapéuticos no regulados: reporte de caso y revisión de la literatura

RESUMEN

El uso de productos fitoterapéuticos y suplementos herbales se ha incrementado, en parte por la percepción de que lo “natural” carece de riesgos. Sin embargo, su consumo puede ocasionar lesión hepática inducida por hierbas (HILI), particularmente cuando se utilizan sin supervisión o circulan como productos falsificados. Se presenta el caso de un hombre de 85 años que consultó por dolor en hipocondrio derecho e ictericia, con lesión hepática de patrón hepatocelular ($R = 11,3$). Durante la anamnesis se documentó el consumo, durante seis meses, de seis productos fitoterapéuticos, entre ellos Redumex, cuyo registro no pudo verificarse, y Vitacerebrina Francesa, lote VTMA513, identificada por el INVIMA como un producto fraudulento con registro sanitario falso. La causalidad se clasificó como posible mediante RUCAM (5 puntos), mientras que la gravedad correspondió a DILIN grado 4.

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Received: 06/3/2026 | Accepted: 09/14/2026 | Published: 09/28/2026

DOI: <http://doi.org/10.51987/Rev.Hosp.Ital.B.Aires.v46i3.1333>

How to cite: de la Rosa MA, Sanabria Vanegas JS, Beltrán Gil G. Severe Liver Injury Associated with the Use of Unregulated Herbal Products: A Case Report and Literature Review. Ciudad Autónoma de Buenos Aires. *Rev Hosp Ital B.Aires.* 2026;46(3):e0001333

<https://ojs.hospitalitaliano.org.ar/>

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ISSN (en línea) 2314-3312

Tras la suspensión de los productos, se observó mejoría clínica y una disminución progresiva de las aminotransferasas y la fosfatasa alcalina, lo que permitió el alta hospitalaria con indicación de evitar la reexposición. Este caso destaca la necesidad de investigar sistemáticamente el consumo de productos herbales y fortalecer la farmacovigilancia y el control regulatorio de productos falsificados.

Palabras clave: Enfermedad hepática inducida por Sustancias y drogas; Preparaciones de plantas; Suplementos dietéticos; Farmacovigilancia; Medicamentos falsificados.

INTRODUCTION

Phytotherapeutic products and herbal dietary supplements are increasingly used. The World Health Organization estimates that approximately 80% of the global population uses traditional medicine, including herbal preparations¹. Marketed as roots, seeds, leaves, teas, powders, oils, creams, capsules, or injectables, these products are favored for their nonprescription access, low cost, and perceived natural safety².

They can cause clinically apparent herb-induced liver injury (HILI), distinguished from conventional drug-induced liver injury (DILI). In the US Drug-Induced Liver Injury Network (DILIN), they constitute approximately 20% of cases³. HILI frequency is likely underestimated because use may be undisclosed and cases unrecognized or unreported²⁻⁴. LiverTox provides updated information on diagnosis, patterns, outcomes, and mechanisms⁵. Regional estimates vary with consumption, populations, definitions, ascertainment, referral, and reporting^{3,6}.

Causality is challenging because products may contain multiple ingredients, vary between batches, and have inaccurate labels. Without a confirmatory biomarker, HILI remains a diagnosis of exclusion based on exposure history, biochemical pattern, alternative-cause assessment, and evolution after withdrawal; management requires discontinuation and clinical and biochemical monitoring^{3,4}.

Although HILI is established, this case is relevant because it involves multiple products of uncertain composition in Colombia, including Vitacerebrina Francesa, lot VTMA513, which INVIMA identified as fraudulent and bearing a false sanitary registration⁷. We describe severe hepatocellular liver injury possibly associated with concurrent phytotherapeutic use and examine causal, clinical, regulatory, and pharmacovigilance implications. This case emphasizes that natural origin and commercial availability do not ensure safety, quality, or authenticity, and supports systematic exposure assessment, regulatory verification, and prompt reporting.

CASE PRESENTATION

An 85-year-old male with a past medical history of cholecystectomy (30 years prior), arterial hypertension,

and hypothyroidism presented to the emergency department. His home medications included levothyroxine 50 mcg daily, enalapril 5 mg daily, which he had received continuously for approximately 30 years, and omeprazole 20 mg daily, which he had taken for one year. He presented with a one-day history of colicky right upper quadrant (RUQ) abdominal pain radiating to the back, associated with jaundice. On physical examination, the patient was in acute pain with generalized jaundice. The abdomen was tender to palpation in the right upper quadrant and epigastrium; the remainder of the physical exam was unremarkable. At admission, his hemodynamic parameters were within normal ranges, with no evidence of hypotension, shock, or tissue hypoperfusion. He reported occasional alcohol consumption limited to social settings.

Initial laboratory findings revealed elevated aminotransferase, alkaline phosphatase, and bilirubin levels (Table 1). Using the laboratory-specific upper limits of normal for ALT (40 U/L) and ALP (115 U/L), the R-value was 11.3, indicating a hepatocellular pattern of liver injury⁴. According to the Drug-Induced Liver Injury Network severity scale, the episode was classified as grade 4 (severe), because the elevation of liver enzymes was accompanied by a total bilirubin of 15.3 mg/dL and an INR of 1.91, thus meeting the criteria of total bilirubin ≥ 2.5 mg/dL and INR ≥ 1.58 . A hepatobiliary ultrasound showed no bile duct dilation or parenchymal abnormalities. Despite the remote history of cholecystectomy, these findings made an obstructive biliary cause less likely. The diagnostic workup showed negative testing for HIV, hepatitis A, B, and C, cytomegalovirus, and Epstein-Barr virus. Testing for hepatitis E and autoimmune liver disease serologies, including antinuclear, anti-smooth muscle, and antimitochondrial antibodies, was not performed.

Upon re-interviewing the patient and his family, a family member confirmed that the patient had been consuming phytotherapeutic products for general malaise and asthenia, together with herbal-based dietary supplements, for six months. Considering the documented exposure, the temporal relationship, and the available diagnostic workup, HILI was considered a possible diagnosis. We discontinued all phytotherapeutic products and omeprazole on admission, while continuing enalapril.

Table 1. The table presents the patient's admission data and the progression of laboratory parameters throughout hospitalization; – indicates the parameter was not measured on that date. AST, aspartate aminotransferase; ALT, alanine aminotransferase; ALP, alkaline phosphatase; PT, prothrombin time; PTT, partial thromboplastin time; INR, international normalized ratio. The laboratory-specific upper limits of normal were 40 U/L for ALT and 115 U/L for ALP. The ALT and ALP results at presentation were obtained on the same date. The R-value was calculated as follows: $R = (1076/40)/(274/115) = 11.3$, consistent with a hepatocellular pattern of liver injury.⁴

Parameter	15/06/2024	20/06/2024	21/06/2024	22/06/2024	23/06/2024	24/06/2024	25/06/2024
AST (U/L)	892	712.9	620.8	570.4	560.4	336.9	259.2
ALT (U/L)	1076	777.2	609.6	561.7	562.7	424.6	369.7
Total bilirubin (mg/dL)	15.30	17.60	19.30	–	19.16	16.87	16.73
Direct bilirubin (mg/dL)	13.60	15.72	16.72	–	16.61	15.14	15.31
Indirect bilirubin (mg/dL)	1.84	2.03	2.68	–	2.54	1.72	1.42
ALP (U/L)	274	–	–	–	204	185	194
PT	20.5	21.7	22.2	21.1	19.1	19.0	–
PTT	32.1	31.2	31.8	31.8	29.0	29.3	–
INR	1.91	2.04	2.09	1.98	1.77	1.76	–

After an initial improvement in liver biochemical tests, omeprazole was reintroduced on hospital day 6 without subsequent biochemical worsening. Aminotransferase and alkaline phosphatase levels decreased progressively throughout hospitalization.

Further investigation revealed that the patient had been consuming six different phytotherapeutic products. Two bore sanitary registration numbers that did not match valid records in the INVIMA database; one of these products was Redumex. The patient also consumed Vitacerebrina Francesa, lot VTMA513, which INVIMA Alert No. 020-2021 specifically identified as a fraudulently marketed product bearing a false sanitary registration⁷. According to the information declared on the product labels, the botanical ingredients included green tea, moringa, garlic, and anamú (*Petiveria alliacea*). However, because some of the products bore falsified sanitary registrations and no chemical analysis was performed, the presence and concentrations of the declared ingredients could not be independently verified.

Based on the available findings, the association between the phytotherapeutic products and the liver injury was classified as possible (RUCAM score: 5), rather than confirmed⁹. Given the improvement in the hepatocellular injury pattern and adequate symptomatic control, the patient was discharged with strict instructions to discontinue all phytotherapeutic products. Table 1 presents the laboratory parameters measured throughout hospitalization, while Figures 1 and 2 show the temporal trends in aminotransferase, alkaline phosphatase, and bilirubin levels.

Post-discharge liver biochemical test results were unavailable for inclusion in this report; therefore, we could not document complete biochemical normalization.

DISCUSSION

The main contribution of this case lies in its local and pharmacovigilance context. Rather than using a single, well-characterized preparation, the patient consumed six commercial phytotherapeutic products, some with sanitary registrations that could not be verified. INVIMA identified Vitacerebrina Francesa, lot VTMA513, as a fraudulent product bearing a false registration⁷. Such products provide no reliable guarantees regarding their actual composition, ingredient concentrations, manufacturing conditions, safety, or efficacy^{4,7}. Although labels listed several botanicals, their presence and concentrations could not be independently verified. Accordingly, simultaneous exposure and compositional uncertainty prevented attribution to one preparation or ingredient. The regulatory alert increased the public health relevance of the exposure but did not establish causality.

The labels declared green tea, moringa, garlic, and anamú (*Petiveria alliacea*), although evidence of hepatotoxicity differs substantially among them. Green tea extract has the strongest documented association with clinically apparent, predominantly hepatocellular liver injury that may occasionally be severe¹⁰. Moringa is classified by LiverTox as a possible but very rare cause, based largely on one case with recurrence after re-exposure¹¹. Evidence for garlic is limited to an isolated report in a liver transplant recipient¹², whereas evidence for anamú is predominantly preclinical and does not establish HILI in humans¹³. Therefore, none of these components can be individually implicated in this patient, particularly given exposure to six products and the uncertain composition of those with falsified registrations.

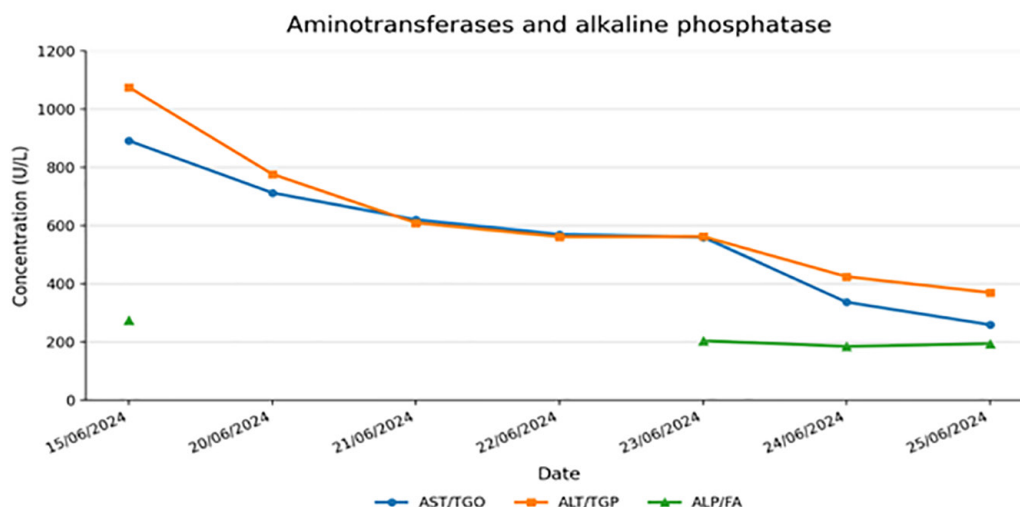


Figure 1. The figure shows the progression of liver function tests during the patient's hospitalization, including AST (Aspartate Aminotransferase), ALT (Alanine Aminotransferase), and ALP (Alkaline Phosphatase).

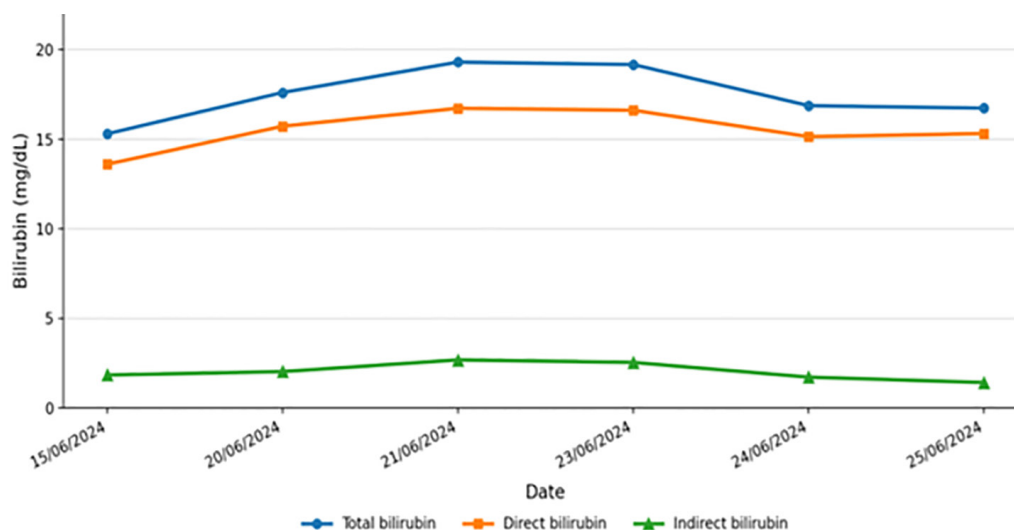


Figure 2. The figure shows the progression of the patient's bilirubin levels during hospitalization, including total bilirubin (TB), direct bilirubin (DB), and indirect bilirubin (IB).

The updated Roussel Uclaf Causality Assessment Method yielded 5 points, corresponding to “possible” causality⁹. Documented exposure, a compatible temporal relationship, a hepatocellular pattern, and progressive improvement after withdrawal supported HILI. However, improvement did not confirm causality because all six products were discontinued simultaneously. Concomitant medications and incomplete exclusion of alternative etiologies further reduced certainty and prevented attribution to a specific preparation. The findings therefore support possible, but not definitive, HILI.

Severity was evaluated independently of causal certainty. The episode met DILIN grade 4 criteria because liver-enzyme elevation was accompanied by total bilirubin of 15.3 mg/dL and INR of 1.91⁸. Thus, “severe” describes clinical magnitude rather than definitive attribution to phytotherapeutic products. Although the hepatocellular pattern had an R-value of 11.3, initial ALP was 2.38 times the upper limit of normal. The case therefore did not meet the traditional biochemical definition of Hy’s Law, which requires ALP below twice the upper limit, and Hy’s Law was not used to determine severity or causality⁴.

The causal assessment considered enalapril and omeprazole. The indication for chronic omeprazole was unavailable. Although both drugs have rarely been associated with idiosyncratic liver injury^{14,15}, enalapril had been used at a stable dose for approximately 30 years. It was continued while liver tests improved, making it unlikely. Omeprazole had been used for one year, was discontinued at admission, and was reintroduced on hospital day 6 after initial improvement without subsequent worsening. Because reintroduction preceded complete biochemical normalization, it was not considered a formally negative rechallenge under RUCAM⁹. Nevertheless, continued recovery made omeprazole less likely than the combined phytotherapeutic exposure.

Important diagnostic limitations remained. Hepatitis E testing and autoimmune serologies, including antinuclear, anti-smooth muscle, and antimitochondrial antibodies, were not performed; these etiologies were therefore not completely excluded. Conversely, normal hemodynamic parameters and the absence of hypotension or shock made ischemic injury unlikely. Occasional alcohol use limited to social settings did not suggest alcohol-associated liver injury. These limitations support the cautious “possible” RUCAM classification^{4,9}.

This case also has health-system implications. Clinicians should routinely and nonjudgmentally ask about herbal products and supplements and document their commercial name, manufacturer, sanitary registration, lot, exposure duration, and place of purchase⁴. Verification against official records may identify fraudulent products, while timely reporting to institutional pharmacovigilance programs and INVIMA can support signal detection, risk communication, and coordinated regulatory action⁷. Community education should challenge the assumption that natural products are inherently safe and encourage disclosure to healthcare professionals.

CONCLUSION

The growing popularity of herbal medicines, coupled with self-medication, underscores the need for rigorous regulation and evaluation of product quality and safety. Beyond the individual clinical event, this case illustrates a potentially preventable public health risk associated with self-medication and the circulation of falsified phytotherapeutic products. Strengthening regulatory surveillance, promoting timely pharmacovigilance reporting, and educating patients and healthcare professionals are essential to improve detection and reduce similar events.

Author contributions: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project

administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft: MAR, JSV. Writing – review and editing: MAR, JSV, GBG.

Conflicts of interest: The authors declare no conflicts of interest related to the content of this article.

Funding: The authors declare that this study received no external funding.

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