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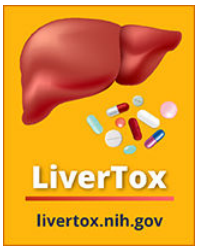


Alpha Lipoic Acid

Updated: May 3, 2023.

OVERVIEW

Introduction

Alpha lipoic acid is a natural occurring essential fatty acid that is synthesized intracellularly, but is also in many foods and absorbed to a variable extent. Alpha lipoic acid is a common ingredient in multivitamin tablets and in dietary supplements and is even included in many pet foods. While purported to have antioxidant, antidiabetic, and antiaging effects, it has not been approved by the FDA as therapy for any medical disease or condition. Alpha lipoic acid has been evaluated in many clinical trials and has not been associated with serum aminotransferase elevations or in cases of clinically apparent liver injury.

Background

Alpha lipoic acid is a natural occurring fatty acid that serves as a necessary, covalently-bound cofactor in many enzymatic processes including the alpha ketoacid dehydrogenases that play a critical role in mitochondria in energy metabolism. Adequate amounts of alpha lipoic acid are synthesized in mitochondria from octanoic acid, but the natural dithiol fatty acid is also found in many foods and can be absorbed from the intestines and taken up in many organs and tissues including liver, kidney, and brain. Alpha lipoic acid has been purported to have antioxidant activity in scavenging free radicals and restoring glutathione levels, as well as antidiabetes activities in normalizing glucose and insulin activity, and as chelating metals. While these pharmacological actions have been found in vitro and in vivo, it is not clear whether alpha lipoic acid supplements have clinically meaningful actions in humans. Multiple studies of alpha lipoic acid in patients with diabetic polyneuropathy, arthritis, diabetes, fibromyalgia, multiple sclerosis, osteoarthritis and other conditions have yielded variable results, but almost invariably with minimal or no adverse side effects. While available in many forms over-the-counter, alpha lipoic acid has not been approved for use by the FDA for any medical disease or condition. In placebo controlled clinical trials in patients with diabetes and peripheral neuropathy, alpha lipoic acid was associated with mild improvements in surrogate markers of neuropathy but was not shown to ameliorate symptoms or progression of neuropathy. Currently, alpha lipoic acid is available in tablets and capsules of 50 to 600 mg and the recommended dosage has ranged from 100 to 600 mg once or twice daily. Alpha lipoic acid is usually well tolerated but side effects at higher doses can include abdominal discomfort, heartburn, constipation or diarrhea, nausea, dizziness, and headache. Rare, potentially severe adverse effects reported after single large overdoses include confusion, stupor, seizures, lactic acidosis, rhabdomyolysis, coma, and multiorgan failure that can be fatal.

Hepatotoxicity

In multiple, largely short term clinical studies of different preparations and concentrations of alpha lipoic acid, adverse side effects were usually described as uncommon and minimal with either no change or slight improvement in serum aminotransferase levels. Despite widespread use, there have been no published reports of serum enzyme elevations or clinically apparent liver injury attributable to alpha lipoic acid given in conventional doses. In cases of overdose of alpha lipoic acid, some patients have developed lactic acidosis, hemodynamic instability, rhabdomyolysis, renal dysfunction, and multiorgan failure, but symptoms of neurologic, cardiac and renal dysfunction generally predominate and liver injury may be the result of shock and ischemia.

Likelihood score: E (unlikely cause of clinically apparent liver injury).

Mechanism of Injury

The mechanism by which alpha lipoic acid might cause liver injury is unknown. In cases of overdose with seizures and lactic acidosis, clinical features suggest that there is generalized mitochondrial failure predominantly affecting the central nervous system, heart, and muscle. The liver histology associated with alpha lipoic acid overdose has not been described but dogs given high doses develop hepatic abnormalities.

Outcome and Management

Hepatotoxicity from alpha lipoic acid has not been reported.

Drug Class: Herbal and Dietary Supplements

Other names: ALA, Thioctic acid.

PRODUCT INFORMATION

REPRESENTATIVE TRADE NAMES

Alpha Lipoic Acid – Generic

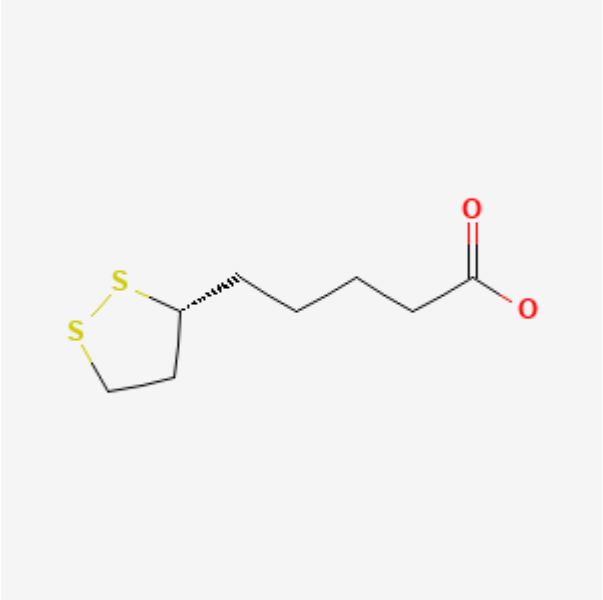
DRUG CLASS

Herbal and Dietary Supplements

SUMMARY INFORMATION

Fact Sheet at MedlinePlus, NLM

CHEMICAL FORMULA AND STRUCTURE

DRUG	CAS REGISTRY NUMBER	MOLECULAR FORMULA	STRUCTURE
Alpha Lipoic Acid (R)	1200-22-2	C8-H14-O2-S2	

ANNOTATED BIBLIOGRAPHY

References updated: 3 May 2023

Abbreviations: ALA, alpha lipoic acid; HDS, herbal and dietary supplements.

Zimmerman HJ. Unconventional drugs. Miscellaneous drugs and diagnostic chemicals. In, Zimmerman, HJ. Hepatotoxicity: the adverse effects of drugs and other chemicals on the liver. 2nd ed. Philadelphia: Lippincott,1999: pp. 731-4.

(Expert review of hepatotoxicity published in 1999; several herbal medications are discussed, but not alpha lipoic acid [ALA]).

Liu LU, Schiano TD. Hepatotoxicity of herbal medicines, vitamins and natural hepatotoxins. In, Kaplowitz N, DeLeve LD, eds. Drug-induced liver disease. 2nd ed. New York: Informa Healthcare USA, 2007, pp. 733-54.

(Review of hepatotoxicity of herbal and dietary supplements [HDS] published in 2007; no mention of alpha lipoic acid).

Alpha lipoic acid. In, PDR for Herbal Medicines. 4th ed. Montvale, New Jersey: Thomson Healthcare Inc. 2007: pp. 935-7.

(Compilation of short monographs on herbal medications and dietary supplements).

Ziegler D, Hanefeld M, Ruhnau KJ, Meissner HP, Lobisch M, Schütte K, Gries FA. Treatment of symptomatic diabetic peripheral neuropathy with the anti-oxidant alpha-lipoic acid. A 3-week multicentre randomized controlled trial (ALADIN Study). Diabetologia. 1995;38:1425–33. PubMed PMID: 8786016.

(Among 328 patients with diabetic peripheral neuropathy treated with ALA [100, 600, or 1200 mg] or placebo intravenously 4 to 5 days per week for 3 weeks, total neuropathy symptom scores improved by 43%, 63% and 58% with ALA vs 38% with placebo, while adverse events were similar with the lower doses as with placebo [14% and 18% vs 21%] but higher with the highest dose [33%]; no mention of ALT levels or hepatotoxicity).

Ziegler D, Schatz H, Conrad F, Gries FA, Ulrich H, Reichel G. Effects of treatment with the antioxidant alpha-lipoic acid on cardiac autonomic neuropathy in NIDDM patients. A 4-month randomized controlled multicenter trial (DEKAN Study). Deutsche Kardiale Autonome Neuropathie. Diabetes Care. 1997;20:369–73. PubMed PMID: 9051389.

(Among 73 patients with diabetic cardiac autonomic neuropathy treated with alpha lipoic acid [ALA: 800 mg] or placebo daily for 4 months, there was ultimately no difference in change in symptoms of autonomic neuropathy although changes in heart rate variability suggested a mild effect; there were no significant adverse events).

Ziegler D, Hanefeld M, Ruhnau KJ, Hasche H, Lobisch M, Schütte K, Kerum G, et al. Treatment of symptomatic diabetic polyneuropathy with the antioxidant alpha-lipoic acid: a 7-month multicenter randomized controlled trial (ALADIN III Study). ALADIN III Study Group. Diabetes Care. 1999;22:1296–301. PubMed PMID: 10480774.

(Among 509 patients with diabetic neuropathy treated with ALA [600 mg] or placebo intravenously for 3 weeks followed by ALA [600 mg] or placebo 3 times daily for 6 months, there were no differences in symptoms of peripheral neuropathy among the 3 groups; adverse events rates were similar in the 3 groups and no mention of ALT elevations or hepatotoxicity).

Ametov AS, Barinov A, Dyck PJ, Hermann R, Kozlova N, Litchy WJ, Low PA, et al; SYDNEY Trial Study Group. The sensory symptoms of diabetic polyneuropathy are improved with alpha-lipoic acid: the SYDNEY trial. Diabetes Care. 2003;26:770–6. PubMed PMID: 12610036.

(Among 120 patients with diabetic neuropathy treated with ALA [600 mg] or placebo intravenously 5 days a week for 14 weeks, symptoms improved more in the ALA treated group, particularly during the final month while rates of side effects were similar in the two groups and "no adverse event was judged to be causally related to the trial medication").

Packer L, Kraemer K, Rimbach G. Molecular aspects of lipoic acid in the prevention of diabetes complications. Nutrition. 2001;17:888–95. PubMed PMID: 11684397.

(Review of the biochemistry and pharmacology of alpha lipoic acid focusing upon differences in update and activity of the two enantiomers of ALA, R and S, and the antioxidant effects of R-ALA and mechanism of action in diabetes, polyneuropathy and vascular physiology).

Cremer DR, Rabeler R, Roberts A, Lynch B. Safety evaluation of alpha-lipoic acid (ALA). Regul Toxicol Pharmacol. 2006;46:29–41. PubMed PMID: 16904799.

(Evaluation of the safety of oral ALA in rats who exhibited no evidence of toxicity except at the highest doses tested [121 mg/kg], which was associated with minor ALT elevations in males and slight changes in liver histology including small droplet fat in periportal regions, but without frank hepatocyte necrosis or inflammation).

Shay KP, Moreau RF, Smith EJ, Smith AR, Hagen TM. Alpha-lipoic acid as a dietary supplement: molecular mechanisms and therapeutic potential. Biochim Biophys Acta. 2009;1790:1149–60. PubMed PMID: 19664690.

(Extensive review of the biochemistry of ALA and the basis for its suspected antioxidant activities and their possible role in diabetes and polyneuropathy).

Solmonson A, DeBerardinis RJ. Lipoic acid metabolism and mitochondrial redox regulation. J Biol Chem. 2018;293:7522–7530. PubMed PMID: 29191830.

(Biochemistry of ALA and review of its role in mitochondrial pathways of energy metabolism).

Cameron M, Taylor C, Lapidus J, Ramsey K, Koop D, Spain R. Gastrointestinal tolerability and absorption of R- versus R,S-lipoic acid in progressive multiple sclerosis: a randomized crossover trial. J Clin Pharmacol. 2020;60:1099–1106. PubMed PMID: 32212340.

(Among 20 adults with multiple sclerosis given either 600 mg of an R enantiomer of ALA or 1200 mg of a racemic mixture of the R and S enantiomers for 7 days and then crossed over to the other dosage, absorption and ALA[R] plasma concentration areas under the curve were similar for the 2 forms but gastrointestinal side effects were greater with the 1200 mg dosage; no mention of ALT levels or hepatotoxicity).

Ziegler D, Ametov A, Barinov A, Dyck PJ, Gurieva I, Low PA, Munzel U, Yakhno N, Raz I, Novosadova M, Maus J, Samigullin R. Oral treatment with alpha-lipoic acid improves symptomatic diabetic polyneuropathy: the SYDNEY 2 trial. Diabetes Care. 2006;29:2365–70. PubMed PMID: 17065669.

(Among 181 diabetic patients with sensorimotor polyneuropathy in Russia and Israel treated with ALA [600, 12000 and 1800 mg] or placebo daily for 5 weeks, symptoms improved more with all 3 doses of ALA compared to placebo [by 48%-52% vs 32%], while adverse events that were more frequent with higher doses of ALA included nausea, vomiting and vertigo).

Jacobsson I, Jönsson AK, Gerdén B, Hägg S. Spontaneously reported adverse reactions in association with complementary and alternative medicine substances in Sweden. Pharmacoepidemiol Drug Saf. 2009;18:1039–47. PubMed PMID: 19650152.

(Review of 778 spontaneous reports of adverse reactions to herbals in a Swedish Registry does not list alpha lipoic acid among products associated with 5 or more reports).

Reuben A, Koch DG, Lee WM; Acute Liver Failure Study Group. Drug-induced acute liver failure: results of a U.S. multicenter, prospective study. Hepatology. 2010;52:2065–76. PubMed PMID: 20949552.

(Among 1198 patients with acute liver failure enrolled in a US prospective study between 1998 and 2007, 133 [11%] were attributed to drug induced liver injury of which 12 [9%] were due to herbals, including several herbal mixtures, usnic acid, Ma Huang, black cohosh, and Hydroxycut, but not ALA).

Ziegler D, Low PA, Litchy WJ, Boulton AJ, Vinik AI, Freeman R, Samigullin R, et al. Efficacy and safety of antioxidant treatment with α-lipoic acid over 4 years in diabetic polyneuropathy: the NATHAN 1 trial. Diabetes Care. 2011;34:2054–60. PubMed PMID: 21775755.

(Among 460 patients with diabetic polyneuropathy treated with ALA [600 mg] or placebo once daily for 4 years, there were no differences in the primary outcomes between the two treatment groups while severe adverse events were more frequent with ALA [38% vs 28%]; no mention of ALT levels or hepatotoxicity).

Teschke R, Wolff A, Frenzel C, Schulze J, Eickhoff A. Herbal hepatotoxicity: a tabular compilation of reported cases. Liver Int. 2012;32:1543–56. PubMed PMID: 22928722.

(A systematic compilation of all publications on the hepatotoxicity of specific herbals identified 185 publications on 60 different herbs, herbal drugs and supplements but does not mention or list alpha lipoic acid).

Bunchorntavakul C, Reddy KR. Review article: herbal and dietary supplement hepatotoxicity. Aliment Pharmacol Ther. 2013;37:3–17. PubMed PMID: 23121117.

(Systematic review of literature on HDS associated liver injury does not mention alpha lipoic acid).

Navarro VJ, Seeff LB. Liver injury induced by herbal complementary and alternative medicine. Clin Liver Dis. 2013;17:715–35. PubMed PMID: 24099027.

(Review of the epidemiology, regulatory status, diagnosis, pathogenesis and causes of liver injury from herbal products with specific discussion of conjugated linoleic acid, ephedra, germander, green tea, usnic acid, flavocoxid, aloe vera, chaparral, greater celandine, black cohosh, comfrey, kava, skullcap, valerian, noni juice, pennyroyal and traditional herbal remedies, but does not mention ALA).

Leung PS, Wang J, Naiyanetr P, Kenny TP, Lam KS, Kurth MJ, Gershwin ME. Environment and primary biliary cirrhosis: electrophilic drugs and the induction of AMA. J Autoimmun. 2013;41:79–86. PubMed PMID: 23352659.

(The antimitochondrial antibody of primary biliary cirrhosis binds to the lipoic acid moiety of the E2 domain of pyruvate dehydrogenase and effectively blocks the activity of the enzyme).

Karaarslan U, İşgüder R, Bağ Ö, Kışla M, Ağın H, Ünal N. Alpha lipoic acid intoxication, treatment and outcome. Clin Toxicol (Phila). 2013;51:522. PubMed PMID: 23713820.

(20 month old boy ingested 4 tablets of ALA [2400 mg] belonging to a patient with diabetes in his home and was admitted 4 hours later with status epilepticus, metabolic acidosis [pH 7.2, lactate 3.9 mmoL] but normal ALT and AST, and resolving within 48 hours with supportive care).

Emir DF, Ozturan IU, Yilmaz S. Alpha lipoic acid intoxication: an adult. Am J Emerg Med. 2018;36:1125.

(A 22 year old woman took an overdose of ALA [18,000 mg] and was found to be confused with severe metabolic acidosis [pH 7.22, lactate 76 mg/dL, ALT 11 U/L, AST 19 U/L, platelets 209,000 falling to 140,000/µL], was treated with gastric lavage, charcoal administration and hydration and recovered within 3 days).

Gulen M, Simsek Y, Oner E, Satar S. First description of the alpha lipoic acid intoxication in an adult patient worldwide following oral administration. Am J Emerg Med. 2018;36:1126.e5–1126.e6.

(38 year old woman took an intentional overdose of ALA [6000 mg] and rapidly developed delirium and metabolic acidosis, thrombocytopenia and rhabdomyolysis [pH 7.26, CPK 174 rising to 5,229 U/L 24 hours later, creatinine 0.84 to 0.93 mg/dL, ALT 17 to 33 U/L, AST 20 to 119 U/L, platelets 189,000 to 64,000/µL, INR 1.24 to 1.4], was treated with supportive care and recovered within 3 days).

Hadzik B, Grass H, Mayatepek E, Daldrup T, Hoehn T. Fatal non-accidental alpha-lipoic acid intoxication in an adolescent girl. Klin Padiatr. 2014;226:292–4. PubMed PMID: 24810749.

(14 year old girl took an intentional overdose of 10 tablets of ALA [6000 mg] and rapidly developed convulsions with metabolic acidosis [pH 6.5, lactate 24 mmoL] progressing to multiorgan failure and dying within 19 hours of admission [platelets 114,000 to 12,000/µL, INR 2.8 to 6 .0, creatinine 1.2 to 2.2 mg/dL, CK 1,059 to 18,383 U/L, ALT 43 to 76 U/L]).

Tolunay O, Çelik T, Kömür M, Gezgin AE, Kaya MS, Çelik Ü. A rare cause of status epilepticus; alpha lipoic acid intoxication, case report and review of the literature. Eur J Paediatr Neurol. 2015;19:730–2. PubMed PMID: 26216607.

(14 month old female developed seizures shortly after ingestion of ALA tablets [belonging to a family member] and was admitted with myoclonus unresponsive to benzodiazepines and metabolic acidosis [pH 7.24, ALT 22 U/L, CK 231 U/L], resolving with supportive care within 2-3 days).

Navarro VJ, Barnhart H, Bonkovsky HL, Davern T, Fontana RJ, Grant L, Reddy KR, et al. Liver injury from herbals and dietary supplements in the U.S. Drug-Induced Liver Injury Network. Hepatology. 2014;60:1399–408. PubMed PMID: 25043597.

(Among 839 cases of liver injury from drugs collected in the US between 2004 and 2013, 130 were due to HDS products, including 45 from body building agents [probably anabolic steroids] and 85 from diverse HDS products, but no case was attributed specifically to alpha lipoic acid).

Brown AC. Liver toxicity related to herbs and dietary supplements: Online table of case reports. Part 2 of 5 series. Food Chem Toxicol. 2017;107:472–501. PubMed PMID: 27402097.

(Description of an online compendium of cases of liver toxicity attributed to HDS products does not list or discuss alpha lipoic acid).

Moretti R, Angeletti C, Minora S. Multiple organ failure and shock following acute alpha lipoic acid (ALA) intoxication. Clin Toxicol (Phila). 2019;57:749–751. PubMed PMID: 30689447.

(70 year old woman developed seizures within 30 minutes after mistakenly taking an industrial form of ALA [4500 mg] with metabolic acidosis, lactic acidosis [14.9 mmoL], decrease in platelets [140,000 decreasing to 73,000/ uL], and hemodynamic instability, responding to supportive therapy within several days).

Medina-Caliz I, Garcia-Cortes M, Gonzalez-Jimenez A, Cabello MR, Robles-Diaz M, Sanabria-Cabrera J, Sanjuan-Jimenez R, et al; Spanish DILI Registry. Herbal and dietary supplement-induced liver injuries in the Spanish DILI Registry. Clin Gastroenterol Hepatol. 2018;16:1495–1502. PubMed PMID: 29307848.

(Among 856 cases of hepatotoxicity enrolled in the Spanish DILI Registry between 1994 and 2016, 32 were attributed to herbal products, the most frequent cause being green tea [n=8] and Herbalife products [n=6], no mention of alpha lipoic acid).

Rahmanabadi A, Mahboob S, Amirkhizi F, Hosseinpour-Arjmand S, Ebrahimi-Mameghani M. Oral α-lipoic acid supplementation in patients with non-alcoholic fatty liver disease: effects on adipokines and liver histology features. Food Funct. 2019;10:4941–4952. PubMed PMID: 31343010.

(Among 50 Iranian patients with nonalcoholic fatty liver disease treated with ALA [600 mg] or placebo twice daily for 12 weeks, changes in serum ALT and AST, body weight and the intensity of hepatic steatosis did not differ in the two treatment arms, although measures of insulin sensitivity and adiponectin levels improved more with ALA treatment).

Hosseinpour-Arjmand S, Amirkhizi F, Ebrahimi-Mameghani M. The effect of alpha-lipoic acid on inflammatory markers and body composition in obese patients with non-alcoholic fatty liver disease: A randomized, double-blind, placebo-controlled trial. J Clin Pharm Ther. 2019;44:258–267. PubMed PMID: 30585337.

(Among 50 obese Iranian adults with nonalcoholic fatty liver disease treated with vitamin E [400 IU] with or without alpha lipoic acid [1200 mg] daily for 12 weeks, serum ALT and AST improved to a similar extent in both groups as did hepatic steatosis, while adiponectin levels increased and insulin and IL-6 levels decreased more in the ALA treated patients; no mention of adverse events).

Dumitru E, Condur L, Alexandrescu L, Chirila S, Greere M, Radu C, Tabacelia D, et al. Triple antioxidant therapy, an alternative for patients with chronic liver disease – a prospective multicenter interventional study. Maedica (Bucur). 2020;15:433–439. PubMed PMID: 33603899.

(Among 1718 adults with nonalcoholic fatty liver treated with a fixed combination of selenium, silymarin and alpha lipoic acid [doses not provided] for at least 24 weeks, hepatic steatosis resolved in 9% and improved in another 59% of patients, while serum ALT fell to normal in 29% of those with elevated values at baseline; no mention of adverse events).

Gilron I, Robb S, Tu D, Holden R, Towheed T, Ziegler D, Wang L, et al. Double-blind, randomized, placebo-controlled crossover trial of alpha-lipoic acid for the treatment of fibromyalgia pain: the IMPALA trial. Pain. 2021;162:561–568. PubMed PMID: 32773602.

(Among 27 patients with fibromyalgia treated in a cross over trial of 5 week courses of ALA [600 mg daily] or placebo, symptoms of fibromyalgia and quality of life were similar in both treatment groups, as were adverse event rates).

Ballotin VR, Bigarella LG, Brandão ABM, Balbinot RA, Balbinot SS, Soldera J. Herb-induced liver injury: Systematic review and meta-analysis. World J Clin Cases. 2021;9:5490–5513. PubMed PMID: 34307603.

(Systematic review of the literature on herb induced liver injury identified 446 references describing 936 cases due to 79 different herbal products, the most common being He Shou Wu [91], green tea [90] Herbalife products [64], kava kava [62] and greater celandine [48]; alpha lipoic acid was not listed among the 79 implicated products).

Bessone F, García-Cortés M, Medina-Caliz I, Hernandez N, Parana R, Mendizabal M, Schinoni MI, et al. Herbal and dietary supplements-induced liver injury in Latin America: experience from the LATINDILI Network. Clin Gastroenterol Hepatol. 2022;20:e548–e563. PubMed PMID: 33434654.

(Among 367 cases of hepatotoxicity enrolled in the Latin American DILI Network between 2011 and 2019, 29 [8%] were attributed to herbal products, the most frequent being green tea [n=7], Herbalife products [n=5] and garcinia [n=3], while alpha lipoic acid was not mentioned).

Ziegler D, Tesfaye S, Spallone V, Gurieva I, Al Kaabi J, Mankovsky B, Martinka E, et al. Screening, diagnosis and management of diabetic sensorimotor polyneuropathy in clinical practice: International expert consensus recommendations. Diabetes Res Clin Pract. 2022;186:109063. PubMed PMID: 34547367.

(Expert consensus recommendations for diagnosis and management of diabetic neuropathy).

Ahmadi M, Keshavarz SA, Abbasi B. Effects of alpha lipoic acid supplementation on serum lipid profile in patients with metabolic syndrome: A randomized, double-blind, placebo-controlled clinical trial. ARYA Atheroscler. 2022;18:1–8.

(Among 46 Iranian patients with the metabolic syndrome treated with ALA [600 mg] or placebo once weekly for 12 weeks, treatment with ALA compared to placebo was associated with significant changes in triglyceride levels [-37 vs +6 mg/dL] and total cholesterol levels [-9 vs + 11 mg/dL] but not in HDL or LDL cholesterol levels; no mention of ALT levels or hepatotoxicity).

Halabi Z, El Helou C, Al Balushi H, Gittinger M, Steck AR, Kaakour A, Abu-Alfa A, et al. Alpha lipoic acid toxicity: the first reported mortality in an adult patient after multiorgan failure. J Emerg Med. 2023;64:190–194. PubMed PMID: 36806430.

(42 year old woman presented 4 hours after an intentional overdose of 6000 mg of ALA and 7.5 gm of acetaminophen with refractory seizures, metabolic acidosis [pH 7.29, lactate 8.79 mmoL], with progressive multiple organ failure and cardiac arrhythmias resulting in death within 26 hours [CPK 848 rising to 14,447 U/L, ALT 15 to 53 U/L, AST 15 to 122 U/L, INR 1.1 to 3.0, creatinine 0.6 to 3.4]).