

Lead in Ayurvedic Remedies: A Warning to Providers

Do your patients use Ayurvedic remedies?

Ayurveda is a medical system from India that is used around the world.¹ Herbs are used in Ayurvedic remedies to promote health or treat disease. These remedies come from Ayurvedic practitioners, from stores or online, and from the United States and other countries. Ayurvedic remedies are available in many forms including capsules, tablets, pills, powders, and liquids. Much of the time, especially when obtained directly from a practitioner, they are compounded and not branded.



Example of Ayurvedic Pill

Heavy metals in Ayurveda



Example of Ayurvedic Pill

Many Ayurvedic remedies have been found to be contaminated with heavy metals such as lead, arsenic, and mercury, and some—called *rasa shastra*—intentionally contain minerals, gems, and sometimes heavy metals.^{2,3} Multiple **Morbidity and Mortality Weekly Reports (MMWR)** have been issued regarding lead poisoning in consumers of Ayurvedic remedies.⁴ Products produced both overseas and in the U.S. may contain metals.

There have been cases in California of lead poisoning associated with the use of Ayurvedic remedies. Most of these cases of lead poisoning occurred in adults, including pregnant women; however, children and infants have also been affected. Laboratory testing of these remedies found lead levels as high as 200,000 micrograms per gram (mcg/g).

The U.S. Food and Drug Administration (FDA) recommended limit for the daily intake of lead from all sources (the Interim Reference Level (IRL)) is:

- ◆ 3 mcg per day for children
- ◆ 12.5 mcg per day for adults

Ayurvedic remedies are **not evaluated by the FDA** for safety, efficacy, or quality before they are sold. While any product considered a “drug,” “food additive,” or “dietary supplement” is subject to some degree of regulation, many supplements and herbal products sold in the U.S., or on the internet, are not reviewed by the FDA.⁵

What is lead poisoning?

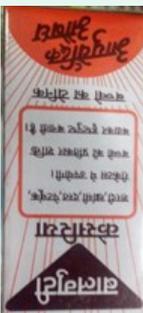
There is no known safe level of lead in the body. Lead can damage the nervous system, renal system, cardiovascular system, reproductive and endocrine systems, and other major organs.

At lower levels a person with lead poisoning may be asymptomatic; however, long-term lead exposure above 5–10 micrograms per deciliter (mcg/dL) increases the risk for health effects such as high blood pressure, kidney disease, cognitive dysfunction, adverse reproductive outcomes, and even death from cardiovascular disease. Higher levels of lead exposure can cause anemia, abdominal pain, nausea, anorexia, and fatigue. Very high levels of lead in the body can cause encephalopathy, seizures, coma, and death.

Children are especially vulnerable to the effects of lead. In children, even low levels of lead in the body can cause a decrease in IQ and problems with learning and behavior. Pregnant women and their unborn babies are also at increased risk from lead exposure, as lead readily crosses the placenta. Increased lead levels during pregnancy are associated with maternal hypertension, spontaneous abortion, decreased fetal growth, premature birth, and adverse neurodevelopmental effects in the infant.



Example of Ayurvedic Pill



Ask your patients whether they take any herbal products or other remedies

If you think that your patient or their family may have been exposed to lead, order a blood lead test, even if they do not exhibit symptoms. A venous blood lead test is the best diagnostic test for lead exposure. A typical adult blood lead level in the U.S. is less than 1 mcg/dL. Blood lead levels at or above the Centers for Disease Control and Prevention (CDC) reference level (currently 5 mcg/dL) are considered elevated, and efforts should be undertaken to remove any sources of exposure.

Kesaria Balguti

Case reports

<p>A pregnant California woman was taking an Ayurvedic remedy for nausea. The mother had a very high blood lead level of over 70 mcg/dL. At delivery, the cord blood was also found to be very high in lead. The Ayurvedic remedy the mother had been taking was tested and found to contain 2,650 parts per million (ppm) of lead.</p>	<p>A California woman was taking three Ayurvedic remedies for three months to increase fertility. The total amount of lead from the three remedies taken as directed was approximately 65,000 mcg/day. The daily lead intake from these remedies was 5,200 times the recommended daily maximum for an adult.</p>
<p>A middle-aged woman with chronic stomach pain consulted with an Ayurvedic practitioner in California. The provider gave her a remedy for her symptoms, which she took for one year. She continued to have pain which became worse, and she told her primary care doctor that she was taking Ayurvedic remedies. Blood lead testing revealed a highly elevated level of 78 mcg/dL. The patient was also found to have anemia.</p>	<p>Several infants in different California counties have had lead poisoning associated with the Ayurvedic remedy Kesaria Balguti.⁶ Information from the packaging identifies this as a tonic pill for babies. In all of these cases, the remedies were purchased in India. The remedies were found to have a lead content of 3,700 - 4,000 ppm. This product has also been associated with cases of lead poisoning in other states.</p>

For more information on:

- ◆ **Lead poisoning in children**, and a list of local childhood lead poisoning prevention programs, visit the CDPH CLPPB website: www.cdph.ca.gov/programs/CLPPB or call (510) 620-5600.
- ◆ **Lead poisoning in adults**, visit the CDPH Occupational Lead Poisoning Prevention Program website: www.cdph.ca.gov/OLPPP or call 1-866-627-1587 (toll-free in CA).
- ◆ Adulterated or misbranded drug products, contact the CDPH Food and Drug Branch at 1-800-495-3232.



Example of Ayurvedic Capsule

For immediate concerns about poisoning call the California Poison Control System at 1-800-222-1222.

¹ Saper RB, Phillips RS, Sehgal A, Khouri N, Davis RB, Paquin J, Thuppil V, Kales SN. Lead, mercury, and arsenic in U.S. and Indian-manufactured Ayurvedic medicines sold via the Internet. JAMA. 2008 Aug 27;300(8):915-23.

² Saper RB, Kales SN, Paquin J, Burns MJ, Eisenberg DM, Davis RB, Phillips RS. Heavy metal content of Ayurvedic herbal medicine products. JAMA. 2004 Dec 15;292(23):2868-73.

³ <https://www1.nyc.gov/assets/doh/downloads/pdf/lead/han-ayurvedic-medications-alert18.pdf>

⁴ <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5326a3.htm>, <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6133a1.htm>, <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6432a6.htm>

⁵ <http://www.fda.gov/regulatoryinformation/guidances/ucm144657.htm>

⁶ <https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm570257.htm>

To obtain a copy of this document in an alternate format, please contact (510) 620-5600. CA Relay Service 711. Allow at least 10 working days to coordinate alternate format services.

