

## Some alternative medicines native to India may cause lead poisoning

We recently received a report about a woman with stomach pains who went to an emergency room for treatment. The woman complained of nausea, vomiting, and diarrhea as well. She had a history of diabetes. She was taking two prescription medicines, **insulin** and **metformin**, at home to control her diabetes. After she was examined by a doctor, blood tests were done. The doctor found that the woman had a very low red blood cell count and an unusually high level of lead in her blood.

The doctor then discovered that the woman was also taking an alternative medicine, Jambroline, which is believed to help control blood sugar. The woman had been taking two pills twice a day for 6 weeks. An analysis of the pills' contents showed that they contained lead. Although the woman had stopped taking the alternative medicine, the amount of lead in her system had accumulated and was causing her symptoms. If left untreated, the lead in her system could have caused serious harm.

Lead and mercury can damage the brain, nervous system, reproductive system, kidneys, and other parts of the body. Mercury can also cause birth defects. Children and pregnant women who use products containing lead or mercury are especially at risk. The woman in this case was given a medicine that binds with the lead and removes it from the body.

Jambroline is a traditional ayurvedic medicine, which is an alternative medicine that originated in India. Ayurvedic medicine involves the use of products such as spices, herbs, vitamins, proteins, minerals, and metals (e.g., mercury, lead, iron, zinc). In this case, the woman had purchased the product during a visit to India, but it is also commonly sold on the Internet and is available in some US stores that sell Indian or South Asian products.

Ayurvedic products, and many other alternative medicine products, do not undergo review by the US Food and Drug Administration (FDA). This means that their safety, quality, and effectiveness cannot be assured by FDA. According to the principles of ayurvedic medicine, heavy metals such as lead, mercury, iron, and zinc, are used because of their reputed therapeutic properties. Indian advocates of ayurvedic medicines say the metals used in products such as Jambroline are purified and rendered harmless. However, improper manufacturing processes may result in dangerously high levels of heavy metals remaining in the final product.

A study published in the *Journal of the American Medical Association* (Saper RB, Phillips RS, Sehgal A, et al. Lead, mercury, and arsenic in US- and Indian-manufactured ayurvedic medicines sold via the Internet. *JAMA*. 2008;300(8):915-23) found that one out of five US-manufactured and Indian-manufactured ayurvedic

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### Check it out!

Follow these guidelines to be safe when taking alternative medicines, which include ayurvedic, homeopathic, naturopathic, and herbal medicines.

✓ **Keep a current list of all the medicines you are taking.** Your list should include prescription and over-the-counter medicines, vitamins, minerals, herbals, and alternative medicines. Be sure to share your updated list with your healthcare providers at every visit.

✓ **Learn about alternative medicines.** Talk to your doctor before taking any alternative medicine. Learn about the benefits as well as the risks and side effects. While most alternative medicines may be safe to use, they can cause problems if too much is taken, if used too long, or if taken with other medicines. Your doctor or pharmacist will be able to tell if it is safe to take these products with other medicines.

✓ **Report use.** Tell your doctors, nurses, and pharmacists about alternative medicines you take, even if you are well. It may change the choice of a medicine your doctor prescribes for you, and allows them to give you advice on which alternative medicines to stop while taking other medicines they prescribe. If you become sick, telling your doctor about alternative medicines you take might help to determine the cause of your illness.

✓ **See a doctor.** Taking an alternative medicine to treat chronic conditions and ongoing symptoms like pain,

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Lead poisoning—continued from page 1 products bought on the Internet contained lead, mercury, or arsenic at levels that exceeded the acceptable daily metal intake. The researchers concluded that several Indian-manufactured products could result in lead and/or mercury ingestions 100 to 100,000 times greater than acceptable limits. Thus, FDA ([www.fda.gov/ForConsumers/ConsumerUpdates/ucm050798.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm050798.htm)), Health Canada ([www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2006/200689-eng.php](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2006/200689-eng.php)), and the European Union ([www.dec.canherald.com/content/134447/ayurvedic-medicines-face-eu-ban.html](http://www.dec.canherald.com/content/134447/ayurvedic-medicines-face-eu-ban.html)) contend that the presence of metals in some ayurvedic products makes them potentially harmful.

Consumers should be aware that some alternative products might contain lead or mercury even if they are not listed as ingredients. A Lead Poisoning Prevention Program promoted by the

New York City Department of Health and Mental Hygiene ([www.nyc.gov/html/doh/html/lead/lead-herbalmед-in.shtml#q2](http://www.nyc.gov/html/doh/html/lead/lead-herbalmед-in.shtml#q2)) has identified the following alternative medicines that are currently known to contain unacceptable levels of lead or mercury:

- **Jambrulin**, made by Unjha Ayurvedic Pharmacy. Used for diabetes and blood sugar control.
- **Mahayogaraj Guggulu Enriched with Silver**, made by Baidyanath. Used for rheumatoid arthritis pain.
- **Lakshmilash Ras (Nardiya)**, made by Baidyanath. Used for chronic fever, cold, and cough.
- **Maha Sudarshan**, made by Arya Aushadhi Pharmaceutical Works. Used for flu and body aches.

To be safe, consumers should avoid taking these products. Also see **Check it out!** in the right column, starting on page 1, for tips on how to use alternative medicines safely.

## Check it out!

**Check it out!**—cont'd from page 1 fatigue, or a persistent rash may seem like a good idea. But don't let it keep you from seeking medical help. Alternative medicines may help relieve symptoms but not cure the illness. A delay in medical treatment could have serious consequences.

✓ **Purchase foreign products with caution.** Use caution when purchasing alternative medicines from foreign countries or over the Internet. If you buy your medicines over the Internet, visit the FDA website at [www.fda.gov/buyonline](http://www.fda.gov/buyonline) for more information. This website has consumer tips for buying medicines safely over the Internet. Discuss questions or concerns you may have with your doctor or pharmacist before you purchase the product.

## Double Trouble

**Lamisil-Lamictal mix-up.** A 9-year-old child with a fungal infection was prescribed **Lamisil (terbinafine)** 250 mg daily for 6 weeks. The child's mother took the handwritten prescription to the pharmacy to get it filled. The prescription was misread by the pharmacist as **Lamictal (lamotrigine)**, a medicine used to control seizures. The pharmacist knew that 250 mg was a high starting dose for **Lamictal**. She could not contact the doctor since his office was closed. So she dispensed 25 mg of **Lamictal** instead. The mother declined to talk to the pharmacist once the prescription was filled. The error was discovered when the mother came in to get a refill of the medicine. The doctor was notified of the error. The child had to slowly be taken off the **Lamictal** to prevent serious side effects caused by abruptly stopping the medicine.

→ **Here's what you can do:** When picking up a prescription, make sure **Double Trouble**—continued on page 3 ▶

## Poison Control



**Medicine that looks like candy poses risk to children.** In December 2010, the US Food and Drug Administration (FDA) issued a warning about potential problems with **Tessalon (benzonatate)**, a medicine used to treat a cough in children over the age of 10. The medicine has a candy-like appearance. It is a round, liquid-filled, gelatin capsule. If left unattended, younger children may eat the capsules thinking it is candy. This can lead to serious side effects such as a heart attack, seizures, and unconsciousness. Since 1982, there have been 5 deaths in children ages 2 years and younger from the accidental



One of the 2011 National Poison Prevention poster contest winners.

ingestion of **Tessalon**. Signs and symptoms of an adverse reaction can occur within 15-20 minutes after taking the medicine, and may lead to deaths within a few hours.

→ **Here's what you can do:** To prevent accidental medicine poisonings, store all medicines in a secure place that is far out of the reach and sight of children. Although prescription medicines often come in child-resistant containers, never rely solely on any kind of packaging to protect your child against accidental poisoning. Never refer to medicine as "candy." Do not keep medicines in purses, diaper bags, or suitcases (when traveling) where children may have access. Remind house-

guests and visitors to do the same. Also, do not take medicines in front of children because kids imitate adults. If you suspect an accidental ingestion, call Poison Control (national toll-free number is: **800-222-1222**) immediately. However, if your child isn't breathing or has collapsed, call 911 immediately.



**Double Trouble**

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you talk to the pharmacist, especially if it is a new medicine. Make sure you know what the medicine is and how it should be taken. Tell the pharmacist *why* you need to take the medicine. This will help prevent mix-ups from occurring, because most medicines with look-alike names are not used to treat the same condition.

**Botox can paralyze unintended muscles**

**Botox Cosmetic (onabotulinumtoxinA)** is a popular form of cosmetic treatment used to reduce signs of aging. The product is injected in small amounts into facial muscles to reduce wrinkles and frown lines. Another form of **Botox** has been approved to treat patients suffering from severe migraine headaches or muscle stiffness and spasticity. Again, the product is injected into the affected muscle to relieve the symptoms.

In most cases, **Botox** treatment is safe. However, both forms of this medicine can cause serious side effects including:

- Severe muscle weakness
- Double vision
- Blurred vision
- Drooping eyelids
- Trouble saying words clearly
- Loss of bladder control
- Trouble breathing
- Trouble swallowing.

Early in 2010, more than 100 cases of serious events with **Botox** were reviewed. In six cases, the patient died. The other reports indicated that **Botox** caused muscle paralysis far from the actual injection site. This resulted in swallowing, speaking, breathing, and bladder control issues. Many of these adverse effects can continue for months after treatment has been stopped.

The US Food and Drug Administration (FDA) believes that **Botox** is safe when it is used for approved conditions and at

the correct dose. However, product information provided for doctors and patients minimize the warning about the medicine's ability to cause distant paralysis. The patient's Medication Guide states: "There has not been a confirmed serious case of spread of the toxin away from the injection site when... **Botox Cosmetic** has been used at the recommended dose to treat frown lines." This statement might lead doctors and patients to ignore warnings about the possible spread of the toxin beyond the site of injection. Such warnings appear in other sections of the product information and Medication Guide. There have also been situations where **Botox** was used for unapproved conditions and at higher than approved doses. The manufacturer of **Botox** products, Allergan, has even been fined for promoting the use of **Botox** for unapproved conditions.

➔ **Here's what you can do:** If you are considering **Botox** treatment for wrinkles and frown lines, ask your doctor to provide you with the Medication Guide for patients. Read it in its entirety and discuss the risks and side effects with your doctor. Ask your doctor about the possibility of other muscles being paralyzed from the injection. If your doctor recommends **Botox** treatment for headaches or muscle stiffness, review the possible side effects you may experience from the treatment. In both cases, inquire about alternative treatment options.

Contact Information

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Advice from FDA  
**Using Malaria Medicine for Leg Cramps is Risky**

**Qualaquin (quinine sulfate)** is a medicine approved by the Food and Drug Administration (FDA) to treat a certain type of malaria, a disease rarely seen in the US. However, people who travel to countries, such as Africa, may become infected with the disease.

In some cases, doctors prescribe **Qualaquin** to treat nighttime leg cramps or restless leg syndrome. This is not an FDA-approved use for this medicine. People using **Qualaquin** to treat or prevent nighttime leg cramps may be at risk for serious and life-threatening reactions. FDA has received reports of side effects—two resulting in death—after people used **Qualaquin** to prevent or treat leg cramps or restless leg syndrome. Side effects included:

- Serious bleeding due to lowered blood cells called platelets
- Permanent kidney damage
- Heart and blood vessel problems
- Hearing loss
- Salt and mineral imbalance.

➔ **Here's what you can do:** **Qualaquin** should be prescribed only to treat malaria. If you currently take it for nighttime leg cramps, discuss other treatment options with your doctor. Contact your doctor immediately if you experience a severe nose bleed, bleeding gums, blood in your urine or stool, or easy bruising.

**FDA** More Advice from FDA can be found at:

[www.fda.gov/ForConsumers/ConsumerUpdates/ucm217599.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm217599.htm).  
Sign up for free email updates at: [https://service.govdelivery.com/service/subscribe.html?code=USFDA\\_9](https://service.govdelivery.com/service/subscribe.html?code=USFDA_9).