Laetrile/Amygdalin (PDQ®)

Overview

• Laetrile is another name for a chemical called amygdalin. Amygdalin is found in the pits of many fruits, raw nuts, and plants (see Question 1).

• It is believed that the active anticancer ingredient in laetrile is cyanide (see Question 1).

• Laetrile is given by mouth as a pill or by intravenous injection (see Question 4).

• Laetrile has shown little anticancer effect in laboratory studies, animal studies, or human studies (see Question 5 and Question 6).

• The side effects of laetrile are like the symptoms of cyanide poisoning (see Question 7).

• Laetrile is not approved by the U.S. Food and Drug Administration (FDA) (see Question 8).

Updated: June 18, 2015

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Laetrile/Amygdalin (PDQ®)

Questions and Answers About Laetrile/Amygdalin

1. What is laetrile?

Laetrile is a compound that has been used as a treatment for people with cancer worldwide. It is not approved by the U.S. Food and Drug Administration (FDA) as a treatment for cancer or any other medical condition. The term “laetrile” comes from 2 words (laevorotatory and mandelonitrile) and is used to describe a purified form of the chemical amygdalin. Amygdalin is a plant compound that contains sugar and produces cyanide. Cyanide is believed to be the active cancer-killing ingredient in laetrile. Amygdalin is found in the pits of many fruits and in raw nuts. It is also found in other plants such as lima beans, clover, and sorghum.

The names laetrile, Laetrile, and amygdalin are often used in place of one another, but they are not the same product. The chemical make-up of Laetrile patented in the United States is different from the laetrile/amygdalin produced in Mexico. The patented Laetrile is a partly synthetic (man-made) form of amygdalin, while the laetrile/amygdalin made in Mexico comes from crushed apricot pits. The studies discussed in this fact sheet used either Mexican laetrile/amygdalin or Laetrile. The generic term “laetrile” will be used throughout this summary except in cases when the patented version of Laetrile is known to have been used in a study.

2. What is the history of the discovery and use of laetrile as a complementary or alternative treatment for cancer?

Amygdalin was first isolated in 1830 and was used as an anticancer agent in Russia as early as 1845. Its first recorded use in the United States as a treatment for cancer was in the 1920s. The early pill form of amygdalin was found to be too toxic, and work with the compound was stopped. In the 1950s, a reportedly nontoxic, partly synthetic form of amygdalin was made and patented in the United States as Laetrile. Laetrile gained popularity in the 1970s as a single anticancer agent and as part of a metabolic therapy program that included a special diet, high-dose vitamin supplements, and pancreatic enzymes (a group of proteins that aid in the digestion of food). By 1978, more than 70,000 people in the United States had reportedly been treated with Laetrile. In 1980, the U.S. Supreme Court upheld a ban on the shipment of laetrile between states in the United States. It is still used in Mexico and at some clinics in the United States.

3. What is the theory behind the claim that laetrile is useful in treating cancer?

Cyanide is thought to be the main anticancer ingredient in laetrile. Two other breakdown products of amygdalin, prunasin (which is similar in structure to Laetrile) and benzaldehyde, may also be cancer cell blockers. The following theories have been proposed to support the use of laetrile for cancer:

- Two of the theories state that the balance of certain enzymes in cancer cells allows laetrile to be toxic to the cancer cells. There is some evidence that normal tissues and malignant tissues do have different amounts of these enzymes.
- Another theory states that cancer is the result of a vitamin deficiency and that laetrile, or “vitamin B-17,” is the missing vitamin needed by the body to restore health. There is currently no evidence that laetrile is needed by the body or that laetrile can act as a vitamin in animals or humans.
- The fourth theory states that the cyanide released by laetrile has a toxic effect that results in killing the cancer cells and stopping them from growing. The theory also states that the damage to the cells causes a boost to the immune system.

4. How is laetrile administered?

Laetrile is given by mouth (orally) as a pill. It can also be given by injection into a vein (intravenously) or muscle. Laetrile is commonly given intravenously over a period of time and then orally as maintenance therapy (treatment given to help extend the benefit of previous therapy).

5. Have any preclinical (laboratory or animal) studies been conducted using laetrile?

Preclinical studies have been done with laetrile either alone or combined with other substances. These studies tested the benefits of laetrile against cancer, the side effects of laetrile treatment, where and how laetrile breaks down in the body, and how laetrile and its breakdown products leave the body. Laboratory and animal studies have shown mixed results on the anticancer effects of laetrile (amygdalin).

Two animal studies of amygdalin by the National Cancer Institute reported no response when it was given alone or with an enzyme that activates the release of cyanide from amygdalin in the body. The animals had more side effects when the enzyme was given at the same time as the amygdalin.
Other studies have reported a response to amygdalin:

- One study reported tumor response in mice when amygdalin was given with enzymes and vitamin A, but not when given alone.
- A second study reported that amygdalin caused white blood cells to have an immune response against prostate cancer cells.
- A third study treated tumor cells with amygdalin and the enzyme that activates the release of cyanide. This study reported that tumor cells became more sensitive to radiation.

6. Have any clinical trials (research studies with people) of laetrile been conducted?

No controlled clinical trials (trials that compare groups of patients who receive the new treatment to groups who do not) of laetrile have been reported.

Although many anecdotal reports (incomplete descriptions of the medical/treatment history of one or more patients) and case reports (detailed reports of the diagnosis, treatment, and follow-up of individual patients) are available, they provide little evidence to support laetrile as a treatment for cancer.

The following has been reported from case series about the use of laetrile in patients with cancer:

- A case series (a group or series of case reports involving patients who were given similar treatment) of 44 patients treated with laetrile was published in 1953. Most of the patients who showed some improvement also received radiation therapy or anticancer drugs, so it is not known which treatment produced the benefit.
- In another series of case reports published in 1962, 10 patients with metastatic cancer (cancer that has spread from one part of the body to another) were treated with a wide range of doses of intravenous Laetrile. Pain relief was the main reported benefit. Reduced swelling of lymph nodes and decreased tumor size were also reported. Long-term follow-up with these patients was not done, however, so it is not known how long the benefits lasted after treatment.
- Benzaldehyde, which is made when laetrile is broken down by the body, has also been tested for anticancer activity in humans. In two clinical series (case reports of a number of patients who are treated consecutively in a clinic), patients with advanced cancer who had not responded to standard therapy were treated with benzaldehyde. Some patients had a complete response (the disappearance of all signs and symptoms of cancer), while some had a decrease in tumor size. The responses to benzaldehyde lasted as long as the treatment continued. Almost all of the patients had been treated previously with chemotherapy or radiation therapy, but it is not known how soon treatment with benzaldehyde began after the other treatment ended.
- In 1978, the National Cancer Institute (NCI) requested case reports from practitioners who believed their patients were helped by treatment with laetrile. Ninety-three cases were submitted; 67 of these were complete enough to be evaluated. An expert panel concluded that 2 of the 67 patients had complete responses and 4 others had a decrease in tumor size. Based on these 6 cases, NCI sponsored clinical studies with laetrile.

Findings from only 2 clinical trials with laetrile have been published. These trials, sponsored by NCI, were done in the late 1970s and early 1980s, and did not include a control group for comparison.

The following has been reported from these 2 clinical trials about the use of laetrile in patients with cancer:

- The first trial, a phase I study, tested doses, schedules, and ways to give amygdalin in 6 cancer patients. Researchers found that amygdalin caused very few side effects when given by mouth or intravenously. Two patients who ate raw almonds while taking amygdalin, however, developed symptoms of cyanide poisoning.
- In 1982, a phase II study with 175 patients looked at which types of cancer might benefit from treatment with amygdalin. Most of the patients in this study had breast, colon, or lung cancer. Amygdalin was given by injection for 21 days, followed by oral maintenance therapy using doses and procedures similar to those in the phase I study. Vitamins and pancreatic enzymes were also given as part of a metabolic therapy program that also included dietary changes. One stomach cancer patient showed a decrease in tumor size, which was maintained for 10 weeks while the patient was on amygdalin therapy. In about half of the patients, cancer had grown at the end of the treatment. Cancer had grown in all patients 7 months after completing treatment. Some patients reported an improvement in their ability to work or do other activities, and other patients said their symptoms improved. These improvements, however, did not last after treatment ended.

7. Have any side effects or risks been reported from laetrile?

The side effects of laetrile treatment are like the signs and symptoms of cyanide poisoning. These include:

- Nausea and vomiting.
- Headache.
- Dizziness.
- Blue color of the skin due to a lack of oxygen in the blood.
- Liver damage.
- Abnormally low blood pressure.
- Droopy upper eyelid.
• Trouble walking due to damaged nerves.
• Fever.
• Mental confusion.
• Coma.
• Death.

The side effects of laetrile appear to depend on the way it is given. Side effects are more severe when laetrile is given by mouth than when it is given by injection. These side effects may be increased by:

• Eating raw almonds or crushed fruit pits.
• Eating certain types of fruits and vegetables, including celery, peaches, bean sprouts, and carrots.
• Taking high doses of vitamin C.

8. **Is laetrile approved by the FDA for use as a cancer treatment in the United States?**

The U.S. Food and Drug Administration (FDA) has not approved laetrile as a treatment for cancer in the United States. The drug is made and used as a cancer treatment in Mexico.

Laetrile compounds from Mexico, which is the primary supplier of laetrile, may vary in purity and contents. Products containing bacteria and other substances and products labeled incorrectly have been found.

**Updated:** June 18, 2015

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