Queensland Government
Queensland Health

Drugs and Poisons: Amygdalin/Laetrile - Questions and Answers

FACT SHEET

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Cancer patients considering complementary and alternative therapies should discuss this with their doctor, because some complementary and alternative therapies may be inappropriate treatments, may interfere with standard treatment, or may be harmful when used with conventional treatment.

Amygdalin is an unproven cancer treatment with an associated risk of cyanide toxicity. It is not registered as a drug for medical treatment in Australia or the United States.

1. What is Amygdalin?

Amygdalin is a plant compound that contains sugar and produces cyanide. It is found in small quantities in the kernels of many fruits and raw nuts. The names Amygdalin and Laetrile are often used interchangeably. The name vitamin B17 is also used to describe this compound, although it is not recognised as a vitamin.

The Australian Government Therapeutic Goods Administration registers medicines marketed in Australia, and this registration requires evidence of the safety, effectiveness and quality of the product. There is no similar assurance of the safety or quality of products such as Amygdalin imported from overseas. Variations in commercial preparations of Amygdalin have been documented in Mexico, which is the primary international supplier of Amygdalin. Incorrect product labels have been found, and samples contaminated with bacteria and other substances have been identified.

2. What is the history of the discovery and use of Amygdalin 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 1920's. The early pill form of Amygdalin was considered too toxic, and work with the compound was discontinued. In the 1950's a semi-synthetic form of Amygdalin was developed and patented in the United States.

3. What controls are there over Amygdalin in Australia?

Amygdalin can be imported into Australia under the Therapeutic Goods Administration Special Access Scheme (SAS), for category A patients ("persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence or early treatment"). In addition, in Queensland a person must not obtain, possess or use Amygdalin without a written approval granted under the *Health (Drugs and Poisons) Regulation 1996* by the Chief Executive of Queensland Health.

4. How is Amygdalin administered?

Amygdalin can be administered by mouth (orally) as a pill. It can also be given by injection into a vein (intravenously) or muscle. Amygdalin is commonly given intravenously over a period of time and then orally as maintenance therapy. Due to concerns about cyanide toxicity following oral administration, Queensland Health issues approvals only for intravenous or intramuscular use.

5. Have any laboratory and animal (preclinical) studies been conducted using Amygdalin?

Preclinical studies have been conducted with Amygdalin either alone or in combination with other substances. These studies tested the benefits of Amygdalin against cancer; the side effects of Amygdalin treatment; where and how Amygdalin breaks down in the body; and they way Amygdalin and its breakdown products leave the body. Laboratory and animal studies have shown little evidence that Amygdalin is effective against cancer.

6. Have any studies of Amygdalin been conducted in people?

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 cancer treatment with Amygdalin.

In a case series published in 1953, 44 cancer patients did not show any measurable response to treatment with Amygdalin. Most of the patients who showed some improvement also received radiation therapy or anticancer drugs, so it is not known how long the benefits lasted after treatment.

Benzaldehyde, which is produced when Amygdalin 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 experienced a complete response (the disappearance of all signs of symptoms of cancer), while some had a decrease in tumour 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.

Despite these unpromising studies, in 1978 the United States' National Cancer Institute (NCI), in an attempt to review cases using strict criteria, sought information about cases in the USA. It sent requests to 385, 000 US physicians and 70, 000 others, together with requests to pro-Laetrile groups, seeking reports of cases believed to have benefited from treatment with Amygdalin. It was estimated that 75, 000 Americans had taken Laetrile at that time. Only 93 "positive" outcome cases were submitted; 67 of these were complete enough to be evaluated. An expert panel concluded that two of the 67 patients had complete responses and four experienced a reduction in tumour size. Based on these six cases, NCI sponsored clinical studies with Amygdalin.

7. What research studies in humans (clinical trials) have been conducted with Amygdalin?

Findings from only two clinical trials with Amygdalin have been published. These trials, sponsored by NCI, were conducted in the late 1970s and early 1980s.

The first trial tested the doses, method of administration, and schedule of administration of Amygdalin in six cancer patients. Researches found that Amygdalin caused minimal side effects. However, two patients who ate raw almonds while taking Amygdalin developed symptoms of cyanide poisoning.

In 1982, a study with 175 patients looked at which types of cancer might respond to treatment with Amygdalin. Most of the patients in this study had breast, colon, or lung cancer. One patient with stomach cancer had a decrease in size of their tumour, which was maintained for 10 weeks while the patient continued on Amygdalin therapy. In 54 percent of the patients, there was a measurable progression (growth) of cancer at the end of the treatment. All of the patients showed cancer progression 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. However, these improvements did not last once treatment ended. On the basis of this study, NCI concluded that no further investigation of Amygdalin was necessary.

No controlled clinical trials (trials that include a comparison group of patients who receive no additional treatment, a placebo, or another treatment) of Amygdalin have been conducted.

8. Have any side effects or risks been reported from Amygdalin?

The side effects associated with Amygdalin treatment are like the symptoms of cyanide poisoning. The symptoms include nausea and vomiting, headache, dizziness, bluish discoloration of the skin due to a lack or oxygen in the blood, liver damage, abnormally low blood pressure, droopy upper eyelid, difficulty walking due to damaged nerves, fever, mental confusion, coma, and death. The risk of side effects can be increased by eating raw almonds or crushed fruit kernels; eating certain types of fruits and vegetables including celery, peaches, bean sprouts, and carrots; or taking high doses of vitamin C.

The side effects of Amygdalin appear to depend on the method of administration. More severe side effects are experienced when Amygdalin is given orally than when it is given by injection.

9. **When considering complementary and alternative therapies, what questions should patients ask their medical practitioner?**

- what benefits can be expected from this therapy?
- what are the risks associated with this therapy?
- do the known benefits outweigh the risks?
- what side effects can be expected?
- will the therapy interfere with conventional treatment?
- is this therapy part of a clinical trial? If so, who is sponsoring the trial?
- will the therapy be covered by health insurance?

10. **What is the view of professional organisations about treatment of cancer with Amygdalin?**

The Medical Oncology Group of Australia (MOGA) is the professional association of specialist medical oncologists (physicians who treat cancer) in Australia. MOGA has made this comment: "MOGA supports the use of evidence based therapy, where appropriately designed clinical trials have demonstrated effectiveness and safety of anticancer agents. Amygdalin/Laetrile would not therefore be appropriate therapy for a patient with cancer, because there is no satisfactory evidence of efficacy, and considerable risk of toxicity.

A 1991 journal article[1] concludes "In light of the lack of efficacy of Laetrile and its demonstrated ability to cause harm, Laetrile should not be used to treat cancer". The article cites the conclusion of the authors of a 1982 study that "Amygdalin (Laetrile) is a toxic drug that is not effective as a cancer treatment". and notes that the American Cancer Society concurs in this judgement.

11. **Where can I get more information about Amygdalin?**

- the US National Cancer Institute provides information about Laetrile/Amygdalin on the internet at: http://www.nci,nih.gov/cancerinfo/pdq/cam/laetrile
- the US National Centre for complementary and Alternative Medicine provides a Questions and Answers cancer facts sheet on the internet at: http://cis.nci.nih.gov/fact/9_3.htm
- an article 'Unproven methods of cancer management – Laetrile' has been published in the journal CA – A Cancer Journal for Clinicians[1].

This fact sheet was developed from a document prepared by the US National Centre for Complementary and Alternative Medicine (http://nccam.nih.gov/).

Further Information:
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[1] Unproven methods of cancer management – Laetrile. CA – A Cancer Journal for Clinicians. 1991;41:187-192