

# Black salve in a nutshell

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## Background

Black salve is an alternative therapy increasingly chosen by patients to self-manage their skin lesions. It is promoted as an effective, safe and natural skin cancer treatment, but such claims are not evidence-based, and serious complications have been reported. The sale of black salve in Australia is illegal.

## Objective

The aim of this article is to educate general practitioners (GPs) about black salve, enabling informed discussion with patients considering using black salve. An overview of the scientific literature is presented.

## Discussion

Case reports have described significant morbidity and even mortality associated with the use of black salve. Despite this, black salve is readily accessible to the public online; a simple internet search yields multiple links to websites endorsing black salve as an effective natural skin cancer remedy. As GPs are often called on in the initial presentation of skin complaints, they are well positioned to ask patients about their use of black salve and educate them about its risks.

**BLACK SALVE** is an alternative topical therapy used to treat skin cancer. It is produced in a variety of formulations; most formulations contain two core ingredients: bloodroot (*Sanguinaria canadensis*) and zinc chloride.<sup>1</sup> Black salve causes skin tissue destruction, resulting in the formation of an eschar of necrotic tissue that eventually sloughs away.

Bloodroot, a North American member of the poppy family, has rhizomes containing a red sap rich in cytotoxic alkaloids,<sup>2</sup> sanguinarine being the alkaloid with the highest concentration. Zinc chloride, a synthetic corrosive chemical, is usually the main black salve ingredient by weight,<sup>3</sup> contradicting the assertion by some vendors that black salve is a 'natural' therapy. Black salve may also contain several other botanical extracts and synthetic compounds. This lack of standardisation and the phytochemical variation inherent in its botanical constituents<sup>4</sup> make black salve a heterogeneous product group with unpredictable clinical effects.

Black salve or its ingredients can be easily ordered by patients through online vendors located in countries lacking regulatory control.

## The history of black salve

In the 1850s, American surgeon Jesse Fell learned of a plant used by Native Americans to treat cancer. He identified this plant as bloodroot and subsequently combined it with zinc chloride to formulate Fell's Paste.<sup>5</sup> On emigrating to London, Fell established a lucrative cancer practice using this paste<sup>6</sup> but was ridiculed as a humbug by many in the medical establishment.<sup>7</sup>

Harry Hoxsey, an Illinois insurance salesman, began selling cancer treatments, including an escharotic in the 1920s. Hoxsey's red paste contained antimony trisulfide, zinc chloride

and bloodroot,<sup>8</sup> and it was reportedly developed after observing horses cure themselves of cancerous lesions by grazing on certain plants. Hoxsey opened 17 clinics across the US, treating several thousand patients in a multi-million dollar enterprise.<sup>9</sup> The American Medical Association branded Hoxsey a charlatan, and the US Food and Drug Administration (FDA) mounted warnings about Hoxsey's formulas in 46,000 US post offices.<sup>10</sup>

Dr Frederick Mohs noted in the 1930s that zinc chloride fixed and histologically preserved skin in vivo. Mohs developed a paste that used stibnite and bloodroot to maintain zinc chloride in suspension, enabling it to act uniformly as a fixative.<sup>11</sup> By microscopically mapping entire tumour margin involvement and excising until clear margins were obtained, Mohs produced cure rates of 99.3% in 7257 cases of basal cell carcinoma (BCC) and 94.4% in 2551 cases of squamous cell carcinoma (SCC).<sup>12</sup> However, these results were not due to Mohs' paste constituents, as evidenced by similar cure rates with the subsequently developed fresh tissue technique where escharotics were not used. Mohs patented his paste to prevent its improper use as a standalone topical therapy.<sup>13</sup>

In 1975, a Portuguese doctor, Almeida Goncalves, visited Mohs' clinic and observed how Mohs' fixative paste technique was performed. On returning to Portugal, Goncalves developed a chemosurgical technique without systematised microscopic control. His process used a paste similar to Mohs', but with galangal (*Alpinia officinarum*) instead of stibnite to facilitate zinc chloride suspension.<sup>14</sup> The salve was applied for 24 hours to lesions as well as a 5–10 mm margin of clinically normal-appearing tissue; biopsies were taken after treatment to assess cancer clearance. Of 179 patients with BCC and 33 patients with SCC, and

with follow-up ranging from five to 10 years, Goncalves reported no recurrences. There was, however, a high failure rate on initial application of 38% in BCC and 21% in SCC, with multiple applications required by some patients. This suggests that patients self-treating with salves are at considerable risk of residual cancer if they do not have histological assessment after salve application.

In the 1990s, Greg Caton formed Alpha Omega Labs, the manufacturer of a black salve formulation that was previously marketed under the brand name Cansema. With a traditional black salve base of bloodroot and zinc chloride, Caton added chapparel (*Larrea mexicana*), graviola (*Annona muricata*) and oleander (*Nerium oleander*).<sup>15</sup> Caton was convicted of mail fraud and the introduction to interstate commerce of unapproved new drugs, violating FDA regulations. After serving a prison sentence, he relocated to Ecuador, where Alpha Omega Labs operates outside US jurisdiction and sells black salve products online to the world.

### Are black salve ingredients cancer-specific?

One in vitro study reported that sanguinarine, the most prevalent alkaloid in bloodroot, possessed cancer-specific cytotoxicity against the A431 SCC cell line in a narrow 2–5 µM concentration range.<sup>16</sup> However, sanguinarine lost cancer specificity at concentrations over 5 µM, being equally effective at killing normal human epidermal keratinocytes. As sanguinarine concentrations show a significant (up to 10-fold) variation between plants,<sup>17</sup> it is unlikely that such a narrow therapeutic window could be targeted by currently produced black salve formulations. Subsequent studies have challenged the cancer specificity of bloodroot alkaloids, finding that human dermal fibroblasts and epidermal keratinocytes are often more sensitive to alkaloid cytotoxicity than human cancer cell lines.<sup>18</sup> Histological examination of a black salve eschar has found both malignant and normal tissue, further debunking claims of cancer specificity.<sup>19</sup>

### Does black salve cure cancer?

There has never been a controlled clinical trial conducted in black salve's 160-year history of clinical use. Current data have been derived from case reports that are by their nature prone to selection bias.

When used as a self-treatment by patients, prognostic outcomes are mixed. Some reports describe histological clearance of biopsy-confirmed SCC and BCC.<sup>20</sup> Follow-up times varied but were generally only up to 12 months and therefore insufficient to determine if long-term cure was achieved. Other patients developed recurrent cancer at the treatment site.<sup>21–23</sup> One patient died as a result of metastasis from a nasal BCC that appeared to have resolved macroscopically with black salve.<sup>24</sup> Another presented with a fungating scalp SCC that had grown despite nine months of black salve treatment.<sup>25</sup> Only two cases of primary melanoma treated with black salve have been reported in the literature; both developed metastatic disease.<sup>26,27</sup>

By contrast, skin cancer excision has been evaluated in multiple trials with highly reliable outcomes. The five-year recurrence-free rates after standard margin excision are 95.2% for primary BCC and 94.6% for SCC.<sup>28,29</sup> Prognosis in melanoma is dependent on tumour thickness, with excision of primary melanomas <1 mm thick resulting in a 96% 20-year survival rate.<sup>30</sup> There is a lack of data regarding the long-term efficacy of black salve and no evidence to support claims that it is superior to conventional treatment for skin cancer.

### Is black salve safe to use?

Black salve has been associated with a number of adverse outcomes (Box 1). The open wound it produces heals by secondary intention, with the limited data available suggesting unfavourable cosmetic results. Among 25 lesions from published case reports, 13 cases (52%) noted scarring.<sup>31</sup> Complications included hypertrophic and keloid scarring requiring scar revision surgery, granulomatous plaque formation requiring topical steroid treatment, and abnormal pigmentation

changes that required biopsy. Five cases (20%) of severe deformity occurred on the nose, secondary to extensive tissue destruction. In two cases, this resulted in complete loss of the nasal ala. Only two lesions were reported as having 'fair-to-good' cosmetic results.

Black salve may also impair the subsequent clinical and histological diagnosis of skin lesions. It is unknown whether skin cancers persisting in black salve scar tissue display dermatoscopic features present in diagnostic algorithms, and histological assessment after black salve therapy can be challenging.<sup>22</sup>

Concerns exist as to whether sanguinarine, the main alkaloid ingredient in black salves, may be a carcinogen. Conflicting in vitro and in vivo results have been reported; some suggest that sanguinarine acts as a genotoxin, operates as a cancer promoter in murine studies and induces leukoplakia when used as a mouthwash ingredient.<sup>32</sup>

### Why do patients use black salve?

Despite regulatory efforts and bad publicity in the media in recent years, black salve continues to be used and distributed in Australia. The exact prevalence of use is unknown. Increasingly, individuals have turned to the internet seeking self-treatment advice for their health problems before consulting a health professional.<sup>33</sup> People may find black salve appealing as it is described as safe, easy to use and natural.<sup>20</sup> It may also be recommended by friends or family members who reportedly

#### Box 1. Reported adverse outcomes of black salve use

- Pain – 'burning' nature, may be intense<sup>25,38–40</sup>
- Abnormal skin pigmentation<sup>22,41</sup>
- Ulceration with delayed wound closure<sup>19,26,40</sup>
- Scarring – ranging from atrophic, hypertrophic to keloid formation<sup>19,22,24,39,41</sup>
- Secondary infection<sup>38</sup>
- Deformity – including nasal cartilage tissue loss<sup>42–45</sup>
- Disease progression to metastasis<sup>24–27</sup>

used it successfully on their own skin lesions. It can also be made in one's home by purchasing the ingredients online.<sup>34</sup>

Many websites about black salve contain information that contradicts conventional medical wisdom. Anecdotes describe how it can cure skin cancer and eliminate moles, warts and skin tags;<sup>35</sup> testimonials ascribe escharotic tissue extirpation as proof that a lesion was malignant and successfully treated. Its appeal has been further enhanced by other anecdotes portraying the failure of traditional medical treatment, including the harms inflicted by doctors treating skin cancer with imiquod and Mohs surgery.<sup>35</sup>

A survey of black salve users showed the most common motivating factor for its use was to avoid surgical treatment because of fears of its failure, adverse outcomes, pain and costs.<sup>36</sup> Another theme identified concerned communication barriers – notably, lack of clinician receptiveness to discuss black salves and fear of being judged by the doctor if the subject was raised.<sup>36</sup> Further research is warranted to explore patients' and doctors' perspectives and experiences with black salve.

### What should I tell patients who are using black salve?

It is illegal to sell or import black salve in Australia, and black salve is similarly banned in the US. In 2012, the Therapeutic Goods Administration warned consumers against purchasing salve products, citing cases of serious

physical harm.<sup>37</sup> Information to discuss with patients is summarised in Box 2.

Patients should be strongly discouraged from experimenting with black salve. As a therapy, it is not natural, it is not cancer-specific, and it causes harm to normal tissue. Patients have had cancer metastasis, excessive scarring, deformity and death as a consequence of using black salve. It is important to deliver such information in a sensitive way within a good therapeutic relationship.

Not all patients follow medical advice. In situations where patients continue to use black salve, a harm minimisation approach is appropriate. Examining lesions prior to black salve use can allow clinicians to strongly advocate for other treatment options, especially for high-risk lesions (suspected melanomas/SCCs; regions prone to metastasis such as the ear and lip; cosmetically sensitive areas) and benign lesions. Patients who use black salve should be offered ongoing regular surveillance of black salve treatment sites, with a low threshold taken for histological assessment.

### Conclusion

Black salve continues to be used by many people in the community, with treatment often being self-initiated without formal medical assessment or advice. Catastrophic consequences can occur. General practitioners should have a high index of suspicion about black salve use and be prepared to discuss its dangers with patients.

#### Box 2. Black salve – Patient information

- Black salve represents a variety of products that are claimed by certain vendors to provide effective treatment for skin cancers.
- Formulations of black salve contain plant extracts, but the main ingredient by weight is zinc chloride, a synthetic corrosive material, and to that extent claims that they are natural therapies are inaccurate. It is also a misconception that natural compounds are safer than and superior to synthetic pharmaceuticals. Some of the most potent poisons known to humankind are natural compounds.
- In the concentrations used in commercially available black salve formulations, these products indiscriminately destroy cancerous and non-cancerous tissue, resulting in a scab that eventually sloughs off and leaves an open wound.
- Serious consequences of black salve use are documented in the scientific literature and include serious scarring, loss of facial structures resulting in severe deformity, and progression of disease, resulting in metastasis to other organs and subsequent death.
- The supply or sale of black salve formulations in Australia is illegal.

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