

Unravelling the confusion around arnica's herbal and homoeopathic use

In this article, **Kevin Leivers** reviews the evidence base for using homoeopathic and herbal *Arnica montana* products and gives pharmacists a rationale for providing impartial and correct information about the product to their patients and customers

Arnica is one of Europe's best selling complementary and alternative medicines (CAM). It is a medicinal herb widely available in the UK and is used in both homoeopathy and herbal medicine to treat a variety of conditions, but most commonly for soft tissue injury, especially bruising. There have been vigorous debates over its evidence base in homoeopathy,^{1,4} and this has sometimes led to the incorrect assumption that clinical research into homoeopathic arnica may be used when assessing the evidence base of herbal arnica products. Despite using the same plant source, the herbal and homoeopathic streams of CAM provide medicines which have fundamentally different formulae. The evidence base supporting each of them must therefore be reviewed separately.

Homoeopathic arnica is commonly available in the form of pillules or tablets to be sucked or chewed. Oral drop formulations are available from specialist pharmacies. Herbal arnica on the other hand is restricted to external use. Accordingly, herbal arnica over-the-counter medicines are most frequently presented as creams, ointments and topical gels. Homoeopathic uses include treatment of the immediate effects of shock, falls, bruising, bleeding and injuries caused by blunt objects, and herbal uses include bruising, soft tissue injury, unbroken chilblains, alopecia neurotica, insect bites and rheumatoid complaints.⁴

Evidence of confusion

There is a significant amount of confusion surrounding CAM among pharmacists and the media. The debates over the evidence base for homoeopathy often affect the public perception of CAM as a whole.

Confusion in the media The media is an ever popular public source of information about CAM. However, it is often the pharmacist who ultimately has to deal with questions or concerns arising from media reports. It is, therefore, imperative that pharmacists are well prepared to deal with these questions, especially when they, in turn, advise their local media. In the case of arnica this lack of clarity is typified by a recent television report² that failed to make a clear distinction between the homoeopathic and herbal medicines containing arnica. During the report,



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Arnica montana flowering plants are used in tincture preparation

pictures showed herbal arnica cream being used by the patient, despite the fact that the clinical trial cited had investigated homoeopathic tablets. The inference from this report was that the public should, in general, be discouraged from using arnica, despite the fact that the trial investigated treatment of carpal tunnel syndrome surgery trauma, not simple first aid use in bruising.

Confusion among pharmacists A 1996 Mintel report showed that over 50 per cent of CAM products are sold through pharmacies.⁵ Further research, funded by the Royal Pharmaceutical Society's Linstead Fellowship, showed that only 40 per cent of pharmacists had received or undertaken any training in CAM.⁵ It is unsurprising, therefore, that some pharmacists appear to be unaware of the existence of evidence supporting a number of CAM modalities and products. In 2002 an article in *The Pharmaceutical Journal* referred to "Baddy Chemists" and stated: "These highly priced placebos compete for much-coveted shelf space with bogus weight-loss pills, pick-me-up tonics and whichever previously unheard-of herbal preparation is this week's miracle cure for arthritis and, just like the homoeopathic pills, these 'remedies' also lack any credible evidence base."³

In a letter to *The Journal*, Peter Houghton, of King's College London, responded: "I fear that he has thrown out some valuable babies with the bathwater in dismissing herbal remedies as quackery and lacking scientific evidence." He also supported the view that "there is much work to be done in establishing sound

evidence base for some herbal medicines", but added "for many common herbal remedies now available, there is an increasing volume of pharmacological and clinical studies that confirm their traditional use".⁶

What is arnica?

In medicinal use, two varieties of arnica are recognised: *Arnica montana* and *Arnica chamissonis*. *Arnica montana* is the most commonly used variety, and either the whole plant (planta tota) or the flowers (flos) are used in tincture preparation. Common names for arnica include Leopard's Bane, Mountain Tobacco and Wolf's Bane. Arnica belongs to the Asteraceae/Compositae family.

Major constituents A significant amount of research on the constituents of arnica and their pharmacological and toxicological effects has been reported.⁴ The flavonoid and terpenoid constituents have been the focus of most of this research, particularly the pharmacological effects of the sesquiterpene lactones.

Preparation of the plant extract The arnica extract (mother tincture) is the building block from which most arnica products are prepared. Both the homoeopathic medicines and the external herbal preparations often use the same mother tincture. Manufacturers usually prepare the mother tinctures according to the Homoeopathic Pharmacopoeia,⁷ which includes the formulas for many plant tinctures in addition to the guidelines for the preparation of homoeopathic medicines.

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Arnica products are typically prepared from an aqueous/alcoholic extract (mother tincture) from the whole plant (*planta tota*) using fresh plant harvested in flower.⁸ The plant is processed immediately in order to avoid degradation. It is steeped in a water/ethanol solution for at least 14 days. The macerated plant is filtered and pressed and the resultant mother tincture assayed before quality control release.

For homeopathic remedies the mother tincture is serially diluted with water/ethanol solution and vigorously shaken (*succussed*) at each stage until the desired potency is reached. In the case of the herbal product the mother tincture is used directly in the cream, ointment or gel base to produce the final product.

Manufacturing standards

Most arnica products (homeopathic and herbal) available in the UK are licensed medicines. Licensed status provides independent assurance of safety and quality of the medicine — the requirements on manufacturers to comply with good manufacturing practice and pharmacovigilance are no different from mainstream manufacturers.

Homeopathic arnica

In homeopathy the mother tincture is serially diluted by a factor of 1 in 10 (for D or X potencies) or a factor of 1 in 100 (for C potencies). After each dilution the solutions are succussed. Potencies are usually prepared in alcoholic or aqueous solutions according to the Homeopathic Pharmacopoeia method,⁸ and then used to impregnate the tablets or pills.

Homeopathic remedies are selected according to the homeopathic law of similars, where the patient is treated with the homeopathic potency that, at a material strength, would cause the same symptoms in a healthy patient. Hence the maxim, “let like be treated by like”.

Homeopathic arnica is one of a small number of remedies referred to as *polycrests*. *Polycrests* are easier to use in self-medication because they are used for specific indications without a detailed match of the patient symptoms to the remedy. In the case of homeopathic arnica the indications are bruising and soft tissue injury.

Generally, a 6C potency is used for chronic conditions such as bruising that is a few days old, and 30C is recommended for acute symptoms. Pillules or tablets are sucked or chewed in a clean mouth (strongly flavoured foods or drinks can interfere with homeopathic products). Full dosage instructions are included on the label.

Higher potencies (eg 200C/1M etc) may be prescribed but are not considered to be suitable for OTC use. These specialist potencies should only be recommended by homeopathically qualified doctors,

homeopaths or pharmacists who have undertaken suitable training. These higher potencies are available through homeopathic pharmacies or suppliers.

The evidence base *Non-clinical study* An *in vitro* study examined the dual inhibition of 5-lipoxygenase (5-LOX)/cyclo-oxygenase 1 and 2 (COX 1 and 2) by a reconstituted homeopathic remedy, Zeel comp N (which contains homeopathic arnica) along with its constituents in herbal strength. The study demonstrated significant inhibitory effects, for the Zeel comp N and the tinctures of *Arnica montana*, *Sanguinaria canadensis* and rhus tox on the production of leukotriene B4 (LBT4) by 5-LOX and on the synthesis of prostaglandin E2 (PGE2) by COX 1 and COX 2 enzymes.⁹

Clinical studies In 1998 Ernst and Pittler conducted a systematic review of placebo-controlled clinical trials involving homeopathic arnica.¹⁰ Eight trials fulfilled the inclusion criteria, investigating the use of homeopathic arnica for delayed-onset muscle soreness (DOMS), prevention of post-surgical dental complications, acute trauma, experimentally inflicted mechanical bruising, and stroke.

Of the eight trials reviewed, two studies (DOMS and prevention of post surgical dental complications) yielded a statistically significant positive result in favour of arnica over placebo. Two studies (both in experimentally inflicted mechanical bruising) produced a numerically positive result in favour of arnica but no formal test statistics were applied. The remaining four studies did not demonstrate a benefit beyond that of placebo (prevention of post surgical dental complications, DOMS, acute trauma and experimentally inflicted mechanical bruising). The reviewers highlighted that there were positive and negative results for the same indications, possibly owing to the variability in the quality of the studies. The effect of the different homeopathic potencies used in these studies could not be quantified. The authors stated that “most of these studies were burdened with severe methodological flaws”, which may have suggested that it was dangerous to draw definitive conclusions. However, the reviewers concluded that “the trials do not suggest that homeopathic arnica is more efficacious than placebo”.

Two recent studies examined the effect of arnica on the pain, bruising and swelling associated with carpal-tunnel release surgery. Jeffrey and Belcher¹¹ compared the combination of homeopathic arnica tablets and external arnica ointment with placebo and found the mean pain visual analogue scores were significantly lower in the arnica group ($P < 0.03$) but no difference between grip strength and swelling. Another randomised

controlled trial evaluated the effect of homeopathic arnica tablets alone and found no significant differences on pain, swelling or bruising.¹²

In addition to these randomised trials there are a number of observational studies, which form part of the wider debate about the significance of outcome studies when reviewing complementary medicines. Birnesser *et al* compared Traumeel S, a proprietary cream that contains a number of homeopathic ingredients including arnica, with standard non-steroidal anti-inflammatory drug therapy on 184 patients with epicondylitis. The results demonstrated significantly superior scores relating to pain at rest and joint mobility for the Traumeel S group.¹³

One conclusion that pharmacists can be clear about is that this debate will continue until better quality clinical research into arnica's homeopathic use is available for review. In the interim, it is likely that health care professionals who support homeopathic arnica will continue to do so. The probability is also that the public will continue to purchase homeopathic arnica from pharmacies.

Herbal arnica

The use of arnica in OTC herbal medicines is fundamentally different from its use in traditional herbalism. Traditional herbalism uses herbal remedies, often in combination, in a holistic way to treat an individual's particular symptoms and characteristics. Phytotherapy (modern herbal medicine) has been defined as the science-based use of standardised plant extracts with known pharmacological activity for the prevention and treatment of specific conditions.

Arnica is widely available as a herbal OTC medicine in the form of creams, ointments, oils and gels in strengths ranging from 0.9–25%v/v tinctures. The OTC preparations are most commonly indicated for the first aid application for all types of bruises resulting from injuries, knocks and falls.

External applications should be applied gently to the bruised areas on children or adults. Arnica preparations should not be applied to broken skin and it is recommended that the treatment be discontinued if a rash appears. All current UK licensed products are on the general sale list (GSL).

The evidence base There are significant pharmacological data to justify the herbal use of arnica.⁴

Non-clinical studies Components of arnica, especially the sesquiterpene lactones helenalin and its related compounds, have been investigated in wide-ranging models of possible anti-inflammatory action. In all studies significant activity was reported.^{14–17} Helenalin and 2,3-dihydrohelenalin inhibited the writhing reflex in mice (an indication of inflammatory pain) by 72 per cent and >40 per cent, respectively. Another study demonstrated the inhibition of transcription factor NF- κ B, a central mediator of the human im-



mune response that regulates the transcription of various inflammatory cytokines such as interleukin-1, -2, -6 and -8 and tumour necrosis factor alpha (TNF- α). Helenalin significantly inhibits NF- κ B activation in response to four different stimuli.¹⁶ This study suggests a molecular mechanism for sesquiterpene lactones that differs from that of other NSAIDs.

A study examined the ability of extracts of *Arnica montana* flowers to impair the activation of transcription factors NF- κ B and NF-AT. The study also examined the effects on the release of the cytokines IL-1 and TNF- α . Overall the study demonstrated that the inhibitory activities relate to the quantitative and qualitative content of the sesquiterpene lactones. The study also found that the inhibitory potency of the 11- α ,13-dihydrohelenalin derivatives was dependent on their esterification.¹⁷

Clinical studies In a randomised, double-blind, placebo-controlled study, 89 patients with venous insufficiency (primary varicosity of the legs) received treatment with arnica gel (20 per cent tincture) or placebo. It was reported that the arnica treatment produced improvements to the venous tone, oedema and to the feeling of heaviness in the legs.⁴ Two other randomised controlled studies investigated this indication.⁸ One study showed a significant greater improvement for the arnica group compared with the placebo group, relating to objective plethysmographic measurements and subjective assessments (feeling of tension and swelling in the legs, pain in the legs). A second identical study demonstrated a significant improvement for both active and placebo groups with no difference between the two.

An open multicentre trial investigated the safety and efficacy of an arnica gel, applied twice a day to 79 patients with mild to moderate osteoarthritis of the knee. After three and six weeks, significant decreases ($P < 0.0001$) were reported in the median total scores on a Western Ontario and McMaster Universities Osteoarthritis Index. Scores on pain, stiffness and function also showed significant decreases. Overall 7.6 per cent of the patients experienced mild to moderate local adverse reactions, which ranged from dry skin to red spots and pruritis.¹⁸

A small study involving 12 male patients found that the external application of arnica flower gel was more effective than placebo in relieving muscle ache.⁸

Safety of herbal arnica The internal use of herbal strength arnica is not recommended. As with nearly all OTC medicines, adverse events are rare. However, topical application of arnica preparations have caused redness, itching and dermatitis.^{5,19} The sesquiterpene lactones have been implicated in contact sensitisation. It is advised that OTC creams, gels and ointments should only be used on unbroken skin. Application should be stopped at the first signs of any reaction.

Meeting ethical guidelines

How can pharmacists meet the Royal Pharmaceutical Society's guidelines for homeopathic and herbal arnica?

With knowledge of the product, the evidence base and the market, a pharmacist should be equipped to decide whether to stock homeopathic or herbal Arnica products. The next stage is to look to the Society's Code of Ethics to guide us.²⁰ It states:

"Pharmacists providing homeopathic or herbal medicines or other complementary therapies have a professional responsibility:

- To ensure that stocks of homeopathic or herbal medicines or other complementary therapies are obtained from a reputable source of supply
- Not to recommend any remedy where they have any reason to doubt its safety or quality
- Only to offer advice on homeopathic or herbal medicines or other complementary therapies or medicines if they have undertaken suitable training or have specialised knowledge"

Selecting a licensed homeopathic or herbal product supplied through a pharmacy wholesaler or direct from a licensed manufacturer will ensure that stocks of these products are from a reputable source with an assurance of safety and quality. UK-licensed homeopathic medicines are labelled with either a PLR (product licence of right) or HR (homeopathic registration) number on the pack. Herbal licensed products such as arnica cream will have a PL (product licence) or PLR number on the pack. It is important to note that all these licences operate with the yellow card scheme for adverse drug reactions.

Both the Centre for Pharmacy Postgraduate Education and the National Pharmacy Association operate courses for pharmacists and assistants on CAM which provide the training required. In addition it is important to follow manufacturers' guidelines for the products that are to be supplied. Many of the licensed manufacturers also supply training courses to support pharmacists and assistants.

Recommending with confidence

Pharmacists have a professional responsibility to ensure that they have sufficient knowledge of CAM to provide accurate advice required by the public and other health care professionals. A recent survey funded by the Royal Pharmaceutical Society has shown that much work is still to be done to achieve this.⁵

When a member of the public requests a CAM product, pharmacists should have the knowledge to advise with precision and recommend with confidence. In the event of the request being for homeopathic arnica, although the evidence for effectiveness remains somewhat equivocal, pharmacists should be confident in selecting a suitable licensed product and giving any necessary advice such as dosage.

In respect of herbal arnica, there is a significant amount of non-clinical and clinical studies supporting its mode of action and clinical usefulness. The evidence suggests that OTC herbal arnica is a useful first aid treatment.

References

1. Schmidt RJ. Same laws of science apply to all medical practices — if only people realised that. *Pharmaceutical Journal* 2003;270:398.
2. Bates P. Arnica's bruised reputation. *Pharmaceutical Journal* 2003;270:p330.
3. Whitaker S. If we endorse quack cures we really deserve to be dubbed "Baddy Chemists". *Pharmaceutical Journal* 2002;268:288.
4. Barnes J, Anderson LA, Phillipson JD. *Herbal medicines. A guide for health care professionals*. 2nd edition. London: Pharmaceutical Press;2002.
5. Barnes J, Kayne S, Berry M, Ernst E. Complementary medicine and the pharmacist. *Pharmaceutical Journal* 1999;263:644–6.
6. Houghton PJ. Valuable babies thrown out with the bathwater (letter). *Pharmaceutical Journal* 2002;268:361.
7. British Association of Homeopathic Manufacturers. *British Homeopathic Pharmacopoeia* 1999. London: Imediacopy; 1999.
8. *Arnicae flos, Arnica flower*. European Scientific Co-operative on Phytotherapy monographs 1997. Thieme: Scientific Foundation for Herbal Medicinal Products; 1997.
9. Jaeggi R, Wuergler U, Grandjean F. Dual inhibition of 5-lipoxygenase/cyclooxygenase by a reconstituted homeopathic remedy; possible explanation for clinical efficacy and favourable gastrointestinal tolerability. *Inflammation Research* 2004;53:150–7.
10. Ernst E, Pittler MH. The efficacy of homeopathic Arnica. A systematic review of placebo-controlled clinical trials. *Archives of Surgery* 1998;133:1187–90.
11. Jeffrey SLA, Belcher HJCR. Use of arnica to relieve pain after carpal tunnel release surgery. *Alternative Therapies in Health and Medicine* 2002;8:66–68.
12. Stevinson C, Devaraj VS, Fountain-Barber A, Hawkins S, Ernst E. Homeopathic Arnica for prevention of pain and bruising: randomised placebo-controlled trial in hand surgery. *Journal of the Royal Society of Medicine* 2003;96:60–65.
13. Birnesser H, Oberbaum M, Klein P, Weiser M. The homeopathic preparation Traumeel S compared with NSAIDs for the symptomatic treatment of epicondylitis. *Journal of Musculoskeletal Research* 2004;8:119–28.
14. Schröder H, Lösche W, Strobach H, Leven W, Willuhn G, Schrör Kl. Helenalin and 11 α ,13-dihydrohelenalin, two constituents from Arnica inhibit human platelet function via thiol-dependent pathways. *Thrombosis Research* 1990;57:839–45.
15. Silk ST, De Marco ME. Identification of a human platelet membrane protein alkylated under conditions inhibitory of phospholipase A2 activity. *Biochemical and Biophysical Research Communications* 1987;146:582–8.
16. Lyss G, Schmidt TJ, Merfort I, Pahl HL. Helenalin, an anti-inflammatory sesquiterpene lactone from Arnica, selectively inhibits transcription factor NF- κ B. *Biological Chemistry* 1997;378:951–61.
17. Klass Christoph A, Wagner G, Laufer S, Sosa S. Studies on the anti-inflammatory activity of phytopharmaceuticals prepared from Arnica flowers. *Planta Medica* 2002;68:385–91.
18. Knuesel O, Weber M, Suter A. Arnica montana gel in osteoarthritis of the knee: an open, multicentre clinical trial. *Advances in Therapy* 2002;19:209–18.
19. Reider N, Komericki P, Hausen BM, Fritsch P, Aberer W. The seamy side of natural medicines: contact sensitization to arnica (*Arnica montana* L) and marigold (*Calendula officinalis* L). *Contact Dermatitis* 2001;45:269–72.
20. Royal Pharmaceutical Society of Great Britain. *Medicines, ethics and practice — a guide for pharmacists* (no 29). London: The Society; 2005.