

Homeopathic Injectables

Importance of the parenteral administration
of homeopathic and anthroposophic remedies

> **RISKS AND BENEFITS**

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> INTRODUCTION

Homeopathic injectables must be manufactured in accordance with the rules of the official EU pharmacopoeia if they claim to be homeopathic. They are used therapeutically in various “special” forms of treatment such as anthroposophy, antihomotoxic medicine, combination homeopathy and classic homeopathy.

More than 120 million ampoules of homeopathic or anthroposophic medicines are now manufactured and distributed in the EU every year. Over 90% of these products are produced by German homeopathic and anthroposophic manufacturers.

The parenteral dosage form was first described in the specialist homeopathic literature in the 19th century [1]. Since then, homeopathic therapists have studied and made practical use of what was at that time, a method of administration completely new to homeopathy [2].

Bergmann [l.c., 2] expressly states that it is advantageous for the homeopathic remedy if it does not have to pass through the gastrointestinal tract where it is severely altered by the gastric and intestinal juices. In this author’s view, potentized homeopathic remedies work best when applied unchanged to the mucosa or - even better - injected under the skin or into the bloodstream.

However, the same author mentions that not all cases of disease can be treated using parenteral administration, and that it is up to the doctor to make the appropriate choice. He also recommends using the “injection method” only when the symptoms of the disease leave no doubt as to the choice of the right “similar” and treatment via the internal (oral) route has failed to have any effect. The new method of administration does not in any way alter the homeopathic character of the remedy in question, the author continues. It also does not alter the validity of the Law of Similars, as is impressively demonstrated by specimen cases.

In the same study the author also describes “injections” of high potencies (D 30 and D 300). The mother tincture was prepared by succussion with water instead of alcohol [l.c. 2, p. 67]. The number of injections given depended on the course of the healing process.

1) Method of administration for homeopathic injectables

As already indicated above, **subcutaneous** and **intravenous** administrations were the first parenteral forms of administrations used in homeopathy. They have been joined in the past 50 years by others such as **intramuscular, intracutaneous, intraarticular and periarticular forms of administration**. These were among other things a result of the introduction of new treatment techniques such as homeosiniatry [3], neural therapy and biopuncture by J. Kersschot [4]. All these invasive techniques exploit the advantage gained by administering the homeopathic

remedy locally, directly to acupuncture points or trigger points. These treatment techniques are used mainly to treat injuries, various types of headache, muscular pain and tendon pain, and acute and chronic inflammatory processes [4].

The main reason for injecting homeopathic solutions into trigger points or into particular acupuncture points is that injecting the homeopathic remedy at that point markedly intensifies the healing effect. In the case of administration at an acupuncture point, the penetration of the injection cannula produces a stimulus similar to that of an acupuncture needle.

11) The advantages of homeopathic injectables

1) No change in the homeopathic substances

Avoiding the gastrointestinal tract by means of injection avoids any change in the homeopathic medicine through the action of either enzymes or the gastric juice. For the same reason, it is well known that solid oral forms (tablets, globules or triturations) or liquid homeopathic remedies (dilutions) should be held in the mouth for at least 30 seconds so that the potentized active substances can be quickly absorbed through the oral mucosa and the direct contact to the enzymes containing saliva is as short as possible. The parenteral form of administration also adheres to the homeopathic principles of the Law of Similars, since any falsification of symptoms is invariably due to the incorrect use of a homeopathic remedy, **it is not a consequence of the method of administration used** (written communication from the German vice president of the LIGA MEDICORUM HOMEOPATHICA INTERNATIONALIS dated 8.12.1990, Dr. med. H. Pötters) [10].

2) No viral or microbial risks

Since every substance for injection in the EU has to meet the sterility requirements of the official pharmacopoeia as stated in the **Parenterals** monograph of **Pharm. Eur. 1997**, a risk of infection from this dosage form can largely be excluded [5, 6]. In accordance with **Method 11, HAB - 2001**, the same requirements also apply to homeopathic liquid dilutions for injection.

3) Better patient compliance

An injection is generally given only by the doctor or therapist.

It is relatively unusual for patients to inject themselves with homeopathic injectables, although there are exceptions such as diabetics and in anthroposophical medicine, where patients inject themselves with s.c. injections.

4) Improved action through injection

When giving injections into acupuncture points or into Head’s zones (segmental therapy) the therapist is exploiting the fact that each segment or each acupuncture point is connected to a particular organ or a region of tissue via the appropriate meridian. Injection here, targets exactly the connected organ or

region of tissue, and this stimulant effect is also supported by the pharmacological action of the injected homeopathic substance. The homeopathic substance may be single-constituent preparation or a combination preparation containing several potentized constituents. This double stimulus - mechanical puncture and the stimulant effect of the homeopathic solution - markedly improves the effect and speeds up healing.

In a survey of 327 doctors conducted by HEEL, Baden-Baden, in 1999/2000 on the practical use of homeopathic injectables, the most frequently cited advantages of the parenteral form of homeopathic medicines compared to the oral dosage form were as follows:

- faster onset of action (77.1%),
- better tolerability (38.5%),
- better control of treatment (57.2%)
- and the ability to administer the substance at the site of the disease (72.8%).

It is interesting in this connection that 61.2% of the doctors surveyed said that the homeopathic injection can readily be combined with other types of treatment (e.g. physiotherapy and/or allopathic medication).

5) Different forms of parenteral administration

5.1) Subcutaneous administration

S.c. injection is the type of parenteral administration first described for homeopathic remedies in the literature [l.c., 1,2].

This type of administration is still the most important for therapeutic practice, as it is the one most frequently used in both homeopathy and anthroposophical medicine.

A survey of medical prescribers was conducted in 1999/2000 by HEEL, Baden-Baden, on the frequency with which parenteral administration was used. A total of 327 doctors in private practice participated: 227 doctors of general medicine and 8 ENT specialists, 17 internists, 51 orthopaedists and 32 doctors in other specialties (more than one answer possible). The survey showed that 72.2% were giving homeopathic injections s.c., followed by i.m., i.v. and i.c. administration. The overwhelming majority (87.8%) had been using homeopathic injectables for more than 5 years. Almost a quarter (24.8%) of the doctors surveyed had been using homeopathic injectables for more than 15 years. Of the 327 doctors who took part in the survey, 62 had an additional

qualification in *homeopathy*, and 179 in *naturopathy*. Other results of this representative survey show, as regards injection sites, that most doses were administered at acupuncture points, trigger points and muscular pain spots. Administration is mostly subcutaneous, much less frequently i.m. or i.c. The injection volumes commonly used are between 0.5 ml and 1 ml and the frequency of injection depends on the type of disease and the course of healing.

5.2) I.v., i.m., i.c., intraarticular and periarticular administration

I.v. administration is used mainly in acute illnesses such as infections, feverish, septic states, collapse [8] and for the excretion of toxins such as heavy metals [9]. Amazing improvements are not infrequently seen in patients shortly after the i.v. administration of the indicated homeopathic remedy [l.c. 8].

I.m. administration is used mainly for rheumatic diseases and conditions which tend to be chronic. Since striated muscle tissue has a good blood supply, it can be assumed that absorption of the remedy is good. Compared to s.c. administration, however, i.m. administration carries a much greater danger of vascular injury, which is why many therapists prefer the less risky s.c. form of administration. In addition, infections and abscesses may occur after intramuscular injection and tissue lesions may be caused by separation of the muscle fibres, resulting in hardening and nodulation in the muscle tissue. This form of administration is extremely rare in anthroposophical medicine.

In **intracutaneous administration** a wheal is created in the corium of the skin; this is produced by injecting 0.1 to 0.2 ml of the drug solution for each wheal. The wheal should not bleed and is usually completely absorbed by the tissue within an hour. This technique is used with homeopathic solutions for hyposensitization and in combination with neural therapy applications. This type of administration plays the smallest role in terms of its frequency of use in practice. Moreover, it is painful and is often rejected by patients sensitive to pain.

We would also mention at this point the **intraarticular** and **periarticular** administration of homeopathic solutions. Intraarticular administration in particular

necessitates prior aseptic treatment of the affected area of the joint into which the substance is to be administered. That is why this type of administration is used mostly by specialists such as orthopaedists, surgeons, rheumatologists, sports physicians and doctors of general medicine [18].

With the **intraarticular** form of administration, however, account must be taken of the residual risk arising solely from manipulation; according to a recent study, this can lead to microtrauma and nonspecific inflammation of the synovial fluid [11] in the joint cartilage, particularly if the injection is repeated within a few weeks, although there is not necessarily a direct connection with a side effect of the homeopathic remedy. For this reason, the authors stipulate that strict diagnosis is needed, plus impeccable aseptic preparation of the site of administration. On the other hand, they [l.c. 11] consider a single intraarticular injection of a small volume to be relatively risk-free, provided aseptic conditions are maintained during manipulation.

By contrast with intraarticular injection, **periarticular** injection given s.c. is virtually risk-free, since the substance solution does not infiltrate the sterile joint cavity but is administered in the form of a wheal created at the painful pressure points around the joint in question [12]. In this study 350 patients were treated with the indicated homeopathic combination product twice a week for 12 weeks. Depending on the type of condition diagnosed, 2-8 ml of the injection solution was administered per treatment. No patient developed side effects of any kind during the treatment.

III) Risks associated with parenteral administration

III.1) Risk reporting

It is undoubtedly right that any invasive use of a drug, such as parenteral administration, will carry some degree of risk. This is equally true of homeopathic and non-homeopathic or allopathic medicines.

So as to formally establish whether and to what extent a risk exists in the use of a drug, the legislators introduced a legal requirement for pharmaceutical manufacturers to document drug risks. Today, thanks to the statutory provisions and the principles of GOOD MANUFACTURING PRACTICE, it is standard international practice to document all

suspected cases of adverse events associated with a drug and to make a medical assessment of every suspected case which comes to light. Each instance must be reported to the competent authority. Specialist committees at the competent authority evaluate all reported cases and take the appropriate action, according to the degree of risk involved, which may in some cases result in the product in question being withdrawn from the market.

The data given below are taken from the databases, logging suspected adverse events, of one homeopathic and two anthroposophic manufacturers in Germany. It should be mentioned that German homeopathic manufacturers alone account for more than 80% of the homeopathic parenterals manufactured in the EU. The figure for the anthroposophic manufacturers is similarly high.

III.2) Type of adverse reactions reported

The reports on adverse reactions, recorded in connection with the injection of homeopathic and anthroposophic injection solutions concerned:

- Local swelling and/or redness (> 90% of reports)
- Local pain (about 8% of reports)
- Allergic reactions (about 2% of reports)
- Severe, life-threatening side effects (e.g. anaphylactic shock) (< 0.1% of reports)
- Nausea (< 0.1% of reports)
- Abdominal pain/colic (< 0.1% of reports).

III.3) Adverse reactions recorded in manufacturers' databases

The following table shows the adverse reactions recorded in the side effect databases of two German anthroposophic manufacturers and the largest German homeopathic manufacturer of parenteral dosage forms. The 10-year data cover the period 1990-1999,

Manufacturer	Number of ampoules sold	Ampoule volume	Mode of administration	Number of adverse reactions
1st anthropos. manufacturer	105 million in 10 years	1 ml and 10 ml	s.c. (98%), i.m. and i.v. (2%)	13
2nd anthropos. manufacturer	80 million in 10 years	1 ml	s.c. (98%), i.c., i.v., i.m. (2%)	23
Homeopathic manufacturer	350 million in 5 years	1 ml and 2 ml s.c.	s.c. (ca. 60%), i.v., i.c., i.m., intraarticular and periarticular (about 40%)	22, of which s.c. 6 times i.v. 2 times i.m. 8 times intraartic. 3 times periartic. 3 times

the 5-year data, the period 1995-1999. The number of adverse reactions recorded for the three manufacturers shown above is very low if the number of adverse reactions is compared with the number of ampoules used.

The percentage proportion of adverse reactions for the homeopathic manufacturer is 0.000036%. It should also be borne in mind that the adverse reactions included in the table relate only to 21 homeopathic combination products, which account for 61.5 million ampoules. However, this manufacturer produced about 350 million ampoules in 5 years; the full ampoule range of this manufacturer covers more than 800 different parenteral homeopathic combination products. It is also noteworthy that there is not a single side effect report for the remaining 290 million or so ampoules produced in the above-mentioned 5-year period.

Similarly low numbers of side effect reports can also be found for the two anthroposophic manufacturers.

III.4) Comparison of risks on the parenteral and oral administration of a homeopathic combination product

In a multicentre post-marketing surveillance study in 3512 patients [13] who received a complex lymphatic remedy in the form of drops and ampoules containing 14 homeopathically potentized active ingredients, evaluation of the adverse reactions after parenteral administration of the product revealed just one side effect in 785 patients, corresponding to an incidence of 0.127%, whereas after oral administration of the same remedy (as drops) 6 adverse reactions were found in 3016 patients (0.198%).

The adverse reactions observed after parenteral administration consisted of local redness, those after oral administration of nausea, vomiting

and diarrhoea. Referred to the individual doses administered per patient, this gives a side effect rate for parenteral administration of < 0.012% and for oral administration of < 0.002%.

Comparison of the results of treatment with the different types of administration (oral and parenteral i.m., i.v., s.c.) revealed the following results for the patients included in the study (n = 3498):

<u>Oral:</u>	75% very good/good; 20% satisfactory; 5% not successful
<u>Parenteral:</u>	80% very good/good; 18% satisfactory; 2% not successful.

The three parenteral types of administration i.m., i.v. and s.c. do not differ to a statistically significant extent as regards the therapeutic success rate:

<u>i.m.</u>	80% very good/good; 17% satisfactory; 3% not successful
<u>i.v.</u>	82% very good/good; 17% satisfactory; 1% not successful
<u>s.c.</u>	78% very good/good; 19% satisfactory; 3% not successful.

In a further prospective post-marketing surveillance exercise with a homeopathic injection product for the treatment of gonarthrosis [14], a side effect rate of 3,7 % was found after intraarticular administration in 1845 patients with knee disorders and a side effect rate of 0,45 % calculated on the basis of the total number of injections given (n = 14460). The side effects were all mild and reversible; thus, no treatment of the side effect was required in 24 cases, and in 15 cases conservative or limited treatment was sufficient, e.g. in the form of ice packs; in a further 29 patients allopathic drugs such as diclofenac, ibuprofen and dexamethasone were also used.

The medical literature describes the intra-articular method of administration in particular as being relatively risky, as has been reported by various authors. The risk of infection after intraarticular administration is, according to Bienvenido et al. [16], 1:7000. Other authors such as Anders [17] give a complication rate of 0.034% after a retrospec-

tive study of more than 650,000 doses given in 99 outpatient orthopaedic indications. Bernau and Köpcke [18] report an incidence of three infections in 105,000 intraarticular injections (about 1:35,000).

In another publication by Weiser in 1997 [15], a prospective post-marketing surveillance study investigated tolerability in the periarticular treatment of gonarthrosis using a homeopathic, parenteral drug with a complex composition. 48 orthopaedists in private practice took part in the study; they treated a total of 643 gonarthrosis patients with the product. Overall, 5 patients (0.8%) showed adverse reactions. Referred to the total number of injections given (n = 5531), this corresponds to a side effect rate of 0.09%.

The adverse reactions recorded were exclusively attributed to local signs of inflammation in the knee region, with 5 cases each of heat and pain, 2 cases of redness, and one case with joint exudate. In 4 of the 5 cases of side effects, antiinflammatories and analgesics plus a cooling treatment using ice were used to treat the symptoms. All side effects were completely reversible.

III.5) Summary

The data currently available demonstrate that both homeopathic and anthroposophic parenteral products have a very low risk of causing side effects. The parenteral administration of homeopathically potentized drugs thus has an extraordinarily low risk potential when administered properly, as is shown by the literature [13-15] and by risk reporting data on adverse events from major homeopathic/anthroposophic manufacturers (see III.1 to III.3).

In contrast, the risk of side effects for allopathic parenterals is much greater [16] and by comparison, homeopathic parenterals can be considered practically hazard-free, according to current risk assessments, particularly in subcutaneous administration.

The parenteral form of administration has clear therapeutic advantages over the oral form, such as the fact that the drug is not altered by the influence of the gastric acid and enzymes in the gastrointestinal tract. Moreover, the parenteral form carries virtually no risk of infection due to the sterility requirements this type of dosage form has to meet. Since

parenteral administration is generally performed by the therapist, patient compliance is high. In addition, the action of the homeopathic parenteral medicine in question can be improved by administration to trigger points, acupuncture points or the “loco dolenti”.

In the author's view, the parenteral method of administering homeopathic / anthroposophic medicines does not carry significant increase in risk of side effects, compared to oral administration when administered appropriately by a therapist, as demonstrated in the outcome study by Riley et al. [19].

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**Permission for translation
by the editor DAZ.
The original article in
German language is
published in DAZ,
Deutsche Apotheker
Zeitung, 142. Jahrgang,
Nr. 29 vom 18.07.2002.**

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