

According to German drug law, medicinal leeches are non-prescription proprietary medicinal products. These products are available for private individuals only in pharmacies. With the exception of internet pharmacies, all sales of leeches through the internet accessible to private individuals are either not selling leeches as a legal medicinal product, or the offer is bogus, fake, or fraudulent.

Advertisement

Biebertaler Blutegelzucht GmbH

Manufacturing authorisation for ingredients of animal origin (leeches), human and veterinary medicinal products is in accordance to Art. 40 and Art. 111 (1) of Directive 2001/83/EC transposed in the following national legislation: Sect 13 paragraph 1 German Drug law (Arzneimittelgesetz – AMG)

Leeches for medical applications are a finished medicinal product as defined in section 2 paragraph 1 no. 1 and section 4 paragraph 1 of the German Drug Law. The production processes adhere to the following quality directives:

- GMP: Good Manufacturing Practice in accordance with the European Quality Directive for Pharmaceutical Producers
- DIN EN ISO 9001:2008 (Quality management system)

Products: Medirud®Biebertal (medicinal leeches)

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- Human therapy
- Animal therapy

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Biebertaler Blutegelzucht

Information on the DGTHA

The purpose of the German Association for the Promotion of Leech Therapy and the Protection of Leeches (DGTHA) is to bring together all parties interested in leeches and their therapeutic use, pooling forces and striving to maintain a balance between medicinal use of leeches and their continued existence in their natural environment.

Further information on the DGTHA is available in German at www.dgtha.de.



DGTHA

Deutsche Gesellschaft zur Förderung
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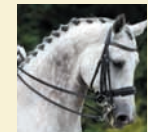
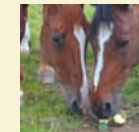
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DGTHA

Deutsche Gesellschaft zur Förderung
der Therapien mit Hirudineen und
ihres Artenschutzes e.V.

DGTHA Information on Leech Therapy in Hoofed Animals



Information Brochure
February 2011

LEECH THERAPY IN VETERINARY MEDICINE

Leech Therapy

Leech therapy is a traditional and recognised treatment of various human diseases. As people have become more and more concerned about the well-being of their sport and recreational animal companions, leech therapy has become increasingly popular in treating their afflictions.

With this brochure, the German Association for the Promotion of Leech Therapy and the Protection of Leeches, the DGTHA, wishes to give an overview of the various possibilities of applying leech therapy in treatment of large hoofed animals such as horses.

Medicinal leeches have a large number of curative active substances in their saliva. These substances are released into the blood and tissue in the course of the sucking process.

The leech can be seen as a living natural pharmacy, full of active

ingredients also used in conventional medicine. However, this natural combination of active leech ingredients is unique. Over the last few decades, modern analytical methods have been able to elucidate the biochemical mechanisms and efficacy of many leech saliva substances. For this reason, German

authorities have classified leeches as a proprietary medicinal product subject to the same regulations on safety, quality, and efficacy as all regulated medicinal products.

The active substances in leech saliva inhibit blood coagulation and enhance blood circulation in the placement area and are particularly active in combatting painful inflammation. The metabolism enhanced by leech therapy can even have a beneficial effect on chronic diseases, raising new perspectives for alleviation and cure.

Leech therapy can effectively be used in the following diseases:

Horses and all other hoofed animals

- Arthritis (e.g. arthritis of joint or ankle)
- Hoof diseases (e.g. equine laminitis, hoof inflammation, hoof rot, hoof hyperplasia)
- Ligament and tendon diseases (tendinitis, tenosynovitis, hoof bulb inflammation, cruciate ligament complaints, patellar dislocation)
- Boils (bursitis, joint or neck boils)
- Necrotic or inflammatory hoof complaints (podotrochlosis)
- Intervertebral disc diseases (e.g. spondylopathy, kissing spines)
- Ataxias (motor coordination disorders)
- Lumbago (back muscles inflammation)
- Myogelosis (muscle stiffness) and myalgia (muscle pain)
- Pressure marks (saddle and harness)
- Eczema (e.g. summer itch, malanders)
- Phlegmon, abscesses
- Mastitis (teat inflammation)
- Wound healing deficits
- Scar healing complications (including post-operative scars)
- Haematoma (bruising)
- Venous diseases (thrombosis, thrombophlebitis)
- Lymphangitis (weed, lymph duct and node inflammation)

What happens in the course of leech therapy?

The treatment of your horse or other hoofed animal usually takes about 60 to 90 minutes. Depending on indication, a single session is often sufficient. At the start of treatment, the leech is placed on the specified skin area, attaches itself and gnaws carefully into the skin with its minuscule teeth. This procedure is nearly painless, as the leech is assumed to release analgesic substances while sawing. Later on (15 to 90 minutes), the leech injects active ingredients into the tissue during the sucking process. When finished, the leech will fall off of its own accord. The small bite injury is kept open by an ingredient called calin (sarin) for 4 to 12 hours during which some blood will continue to ooze. The healing effects occur after varying time spans, often immediately following treatment. The effects frequently last for months.

How does your horse or other hoofed animal react to the leech bite?

As a rule, horses and other hoofed animals accept the leech bite without any signs of resistance and usually tolerate the treat-



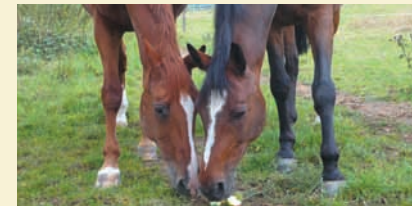
ment patiently. The healing efficacy of the leech bite has obviously become rooted in their instincts in the course of evolution. Many animals will snooze calmly during treatment.

What is necessary for the aftercare?

If wound impurities can be avoided, the wound can be kept open to allow blood to continue to ooze. If necessary, an absorbent bandage may be applied to the wound.

What are the risks for your horse or other hoofed animal?

Adverse drug reactions are very rarely observed in leech therapy performed on animals. In principle, the risk of wound infections or allergic reactions has to be considered.



In addition, the animal

might be sick with diseases precluding the use of leech therapy. For these reasons, the DGTHA recommends leech therapy be performed only by a trained professional or under the strict supervision thereof.

Animals used as a food supply

As leeches are not currently approved as a medicinal product for the treatment of animals used as a source of food, leech therapy may only be performed with a reappraisal, done by a veterinarian, in accordance with § 56 of German Drug Law (Arzneimittelgesetz).