



1. Permission of leeches as finished medicament: Questionnaire for the treatment of illnesses with leeches
2. New package insert
3. Price adjustment to 01. March 2007
4. Seminar plan 2007
5. Report to the work of the DGTHA
6. New practice literature about leeches

---

Very honoured customers,

2006 presents itself in the review as a very turbulent year. Apart from the introduction of a quality assurance system for medical leeches by the BfArM, the Deutsche Gesellschaft zur Förderung der Therapien mit Hirudineen und Ihres Artenschutzes e.V. (DGTHA) was founded (German society for the support of therapies with leeches and their protection for endangered species). Beyond that since long years a comprehensive book was published concerning the therapy and science of the leeches, which contacts very purposefully practical men, to which also school-medical bases are important. This leech info sheet reports to aforementioned and further topics.

1. Permission of the leeches as finished medicament: Questionnaire for the treatment of illnesses with leeches

The Biebertaler Blutegelzucht stands before the task of the permission of the medical leech as finished medicament in 2008. This requires the scientific proof of its medical quality, security and effectiveness. Apart from other proofs clinical studies are necessary for the individual indications, for which the permission is aimed at. Due to the broad indication pallet with which leeches are used, it is impossible at short notice to accomplish clinical studies for all indications.

For the permission we developed two questionnaires (human therapy/animal therapy) in cooperation with interested federations of the health service, in order to receive an evaluation basis of practical applications of leech therapy as broad as possible. With this questionnaire the therapist is given the possibility to bring in therapy results for the procedure of permission. The questionnaires are temporarily attached to the Leech info sheet and/or can be called up and printed out on our homepage [www.blutegel.de](http://www.blutegel.de) / [www.leech.de](http://www.leech.de) .

If many experienced therapists would document and send us 2 - 3 cases of therapy in 2007, a substantial database would accumulate, which could not be ignored in the procedure of permission. An evaluation and publication of the results would also give a practical assistance for the application of the leech therapy to the therapists. The necessary work

would take place within the tasks of the DGTHA (see also point 5 of the leech info).

We would be pleased, if you would take part in this project!

2. New package insert

In the context of the conversion of the quality assurance system for medical leeches for the human therapy (default of the Federal Institute for medicaments and medicine products since October 2006) also the development of a more differentiated package insert (customs information) was necessary, which must correspond to the formally closely specified defaults of the medicament right.

Regarding the conversion of the requirements from the quality assurance system, the new packet insert is checked and admitted by the federal institute of medicament and medicine products (perhaps it can still last some days after appearance of the present leech info until the new packet insert is enclosed to the leech deliveries or can be called up on the Internet under [www.blutegel.de](http://www.blutegel.de) or [www.leech.de](http://www.leech.de) , column downloads).

Due to the information extension and the new medicament-legal requirements, we also ask all experienced therapists to read the new package insert carefully and to convert the tips within the therapy.

3. Price adjustment to March 01, 2007

With leech info 2/2005 we had announced price adaptations in the coming years - so far as necessary - in each case to the 1st January. Now the prize adaptation for 2007 occurs only to the 1st March, because the changes of the production costs on account of the new quality assurance system (a guidance since October, 2006) as well as the upcoming licensing costs as a ready medicament and with this the calculation of the new leech prices was possible only with the experiences of the 1st quarter of 2007. The production costs for the leeches have increased massively. Within the range of small quantities we could catch the costs with a still relatively moderate rise of approx. 18%. With large order quantities we could offer considerable discounts in the past. On account of the clearly risen cover costs we had to change the offer structure and diminish the discounts for larger order quantities. The medical leeches of the Biebertaler Blutegelzucht - which up to now after our knowledge has received the medicament-juridical production permission as the only leech breeding in Europe - remain favourable in the European prize comparison furthermore.

4. Seminar Plan 2007

For 2007 we have planned the following seminars to the leech therapy in Biebertal near Gießen:



Datum	Seminartitel
31.03.2007	Base seminar for animal therapists
02.06.2007	Base seminar for human therapists
03.06.2007	Progressing seminar for human therapists
15.09.2007	Base seminar for human therapists
17.11.2007	Base seminar for animal therapists
08.12.2007	Base seminar for human therapists

The subjects of the seminar for advancers are announced within the next weeks on the Internet. After the positive experiences with the double seminar in 2006 we have laid the topic seminar once more on a Sunday in the direct connection to the base seminar on Saturday in order to allow the seminar visit as a combination arrangement to the groups of the therapy novices and if necessary also of the advancers. We ask you to do reservations on our internet side [www.blutegel.de](http://www.blutegel.de) / [www.leech.de](http://www.leech.de) on which the next seminar dates as well as the topic seminar are announced.

## 5. Report to the work of the DGTHA

The Deutsche Gesellschaft zur Förderung der Therapien mit Hirudineen und ihres Artenschutzes e. V., DGTHA (German society for the support of therapies with leeches and their protection for endangered species inc.) has held in 2006 two meetings of the board of directors and the foundation members beside the foundation meeting on the 26th April, 2006. Among other things, an association advisory board was brought to life which observes and evaluates the topical political and scientific developments of the leech therapy, and presents suggestions for the association work.

In addition, a study group was founded to the pharmacovigilance and the known cases of side effect in 2006 were evaluated. The study group had to classify none of the announced suspicion cases as a "heavy side effect". Beyond it, the foundation of a study group is planned for the area of the animal therapy with leeches. The new Internet page of the DGTHA will be available under [www.dgtha.de](http://www.dgtha.de) from 5th March, 2007 for interested visitors and the work of the members.

Already in autumn 2006, a new book has appeared to the leech therapy in the HAUG publishing house which especially puts the practise relation of the leech therapy for therapists into the centre. This book shows you the bases, methodology and application possibilities of the leech therapy. The main focus lies on indication areas already occupied by scientific studies. You profit from concrete instructions for the leech therapy and learn to know the spectrum of the possibilities, but also the borders of the procedure. The assessment of the procedure for the single indications helps you to estimate the therapy choice more certainly.

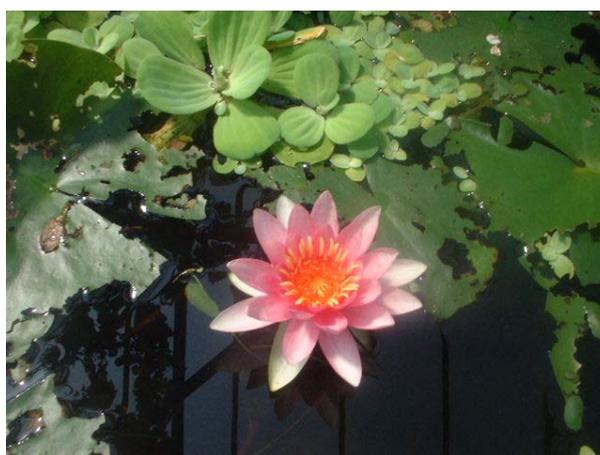
A. Michalsen, M. Roth (Editors.)

Blutegeltherapie  
2006, 146 S., 52 Abb., 3 Tab., kt.  
€ [D] 34,95  
ISBN-10: 3-8304-7169-6  
ISBN-13: 978-3-8304-7169-1

In January, 2007 the English version was published in the Thieme publishing house.

A. Michalsen, M. Roth, G.J. Dobos  
Medical Leech Therapy  
200 pages, 40 illustrations, Softcover  
ISBN 978-3-13-143581-1  
€ 39.95

Both books can be bought in book trade and are not available from the Biebertaler Blutegelzucht!



Spring impression at the Biebertaler Blutegelzucht

28.02.2007  
revised on 06.03.2007

---

Imprint:

Conductor of business premises:  
Dr. rer. nat. Manfred Roth (expert after §14 AMG and production leader),  
Diploma biologist Michael Aurich

Management: Monika Neumaier