

Information on Quality Assurance Requirements of Storing Blutegel Medirud®¹

Dear User,

we kindly ask you to adopt the following measures immediately upon receipt of the leeches.

The quality assurance measures aim to maintain the quality of leeches until the therapeutic use.

In case of non-compliance to these standards, a loss of quality of the medicinal leeches might induce an increased risk of adverse events occurring.

In the event of abnormal appearances or death of your leeches, photos must be attached to your complaint. Without photos, we will not be able to process your claim. Thank you for your understanding.

Quality Assurance Requirements

Specific conditions of storing medicinal leeches must be observed before starting the therapeutic use.

Immediately upon Receipt
<p>› The leeches must be taken out of the transport packaging immediately upon receipt and transferred into a receptacle (tightly closed) filled with $\frac{3}{4}$ of clean water. The leeches should be rinsed with luke-warm tap water before placing into the receptacle. Any mucous adhesions to the leech are harmless, forming a natural protective layer.</p>
<p>› Leeches are very agile → Tight closure is essential. Preserving jars or big jars with screw-caps or clamping fasteners can be used as tightly closing receptacles. The oxygen content in the aforementioned receptacles is sufficient for the medicinal leeches. Air holes in the lid are not necessary.</p>
<p>› Distilled water should be used as jar water². Per 1 litre of distilled water, add approx. 0.5 g of additive-free table salt or sea salt. When using tap water for leech keeping, no chlorinated (potentially harmful) water should be taken. Since chlorination cannot always be ruled out, low-risk husbandry with distilled water is recommended.</p>
<p>› Leeches tend to slough their skins every 2-3 days. Accordingly, the placement of several sharp-edged stones in the jar is recommended (The stones should be boiled for germ reduction before the placement).</p>
Additional Optimal Conditions of Leech Storing
<p>› Leeches are sensitive to disturbances. The optimum storage of the jar is a quiet and dark place protected from vibrations. Cool storage (5 – 8 °C) reduces the potential germiness.</p>
<p>› A maximum of 5 medicinal leeches can be kept per one litre of water. No more than 10 medicinal leeches should be kept in one receptacle.</p>
<p>› Water should be changed every 2 days. Before changing the water, the temperature of the changing water should be adjusted to the temperature level of the holding water. Receptacles must be cleaned after 14 days at the latest or before a new supply of leeches is introduced. Glass containers can be cleaned in the dishwasher (at least 60 °C) and, if necessary, disinfected with common surface sanitisers (isopropanol, ethanol). After the use of sanitisers, the receptacle must be rinsed carefully with water before the reset of the leeches. The disinfection process has to be documented.</p>

¹⁾ Medicinal leeches of bbez: Wild cultured leeches and bred leeches for therapeutic use.

²⁾ **Background information on storage water (receptacle):**

Tap water exceeding water hardness of 3 (hard) or approx. 14° dH respectively is inappropriate for keeping medicinal leeches due to the alkaline pH value of hard water. An alkaline pH value exceeding 7.5 pH induces the conversion of the excretion substances of medicinal leeches into toxic ammoniac.

Leeches are very sensitive to inadequate storage conditions!


Specific Storage Conditions:		
Storage Parameters	Short-term Storage (up to 7 days approx.)	Long-term Storage (Exceeding 7 days)
Light:	No direct sunlight; <i>ideal:</i> dimmed	Dimmed
Temperature:	5 °C up to 18 °C maximum	5 °C up to 8 °C (Fridge ³⁾)
Water Change:	Every second day	Weekly
Quantity per litre	Maximum 5 leeches	Maximum 5 leeches
Quantity per receptacle	Maximum 10 leeches of equal size	Maximum 10 leeches of equal size

³⁾ Cool storage reduces germ development.

Use of Blutegel Medirud®

Quality Requirements for Therapeutic Use

The following measures are recommended:

- › After delivery, the leeches should rest in their new environment for 1 to 2 days before they are used therapeutically.
- › The *water temperature* of the receptacle should be adjusted to room temperature *at least 2 hours* before treatment. Please place the receptacle in the room prior to use. Do not pour in warm water for adjustment.
- › The leeches must be rinsed for 5 minutes *directly before treatment* with luke-warm tap water. This measure is intended to remove potential germs from the leech skin.
- › *Place of treatment:* No nicotine, ethereal oils, glaring lamplight or thunderstorms. Leeches react sensitively to vibrations or odours leading to hesitant or complete reluctance of biting. Accordingly, these sources of disturbance should be excluded before and after treatment.
- › Use only leeches with vital appearance.
- › Leeches should be applied using a shot glass upside down, short cut plastic syringe, or applicator.
- › Leeches must not be used a second time! 
- › Please read the package insert information on the disposal of the used leeches.

For your current notifications/notes:



BIEBERTALER BLUTEGELZUCHT

Biebertaler Blutegelzucht GmbH | Talweg 31 | D-35444 Biebertal
tel 06409 66140-0 | blutegel@blutegel.de | www.blutegel.de

Production conforming with GMP Guidelines (Production
Standards of European Medicines Manufacturers) and
DIN EN ISO 9001:2015