

## Information on Quality Assurance Requirements of Storing Blutegel Medirud®<sup>1</sup>

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 to [blutegel@blutegel.de](mailto:blutegel@blutegel.de). Without photos, we will not be able to process your claim. The complaint period is 8 days from the date of shipment. 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 <math>\frac{3}{4}</math> of clean water. <b>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.</b></p>
<p>› Leeches are very agile → <b>Tight closure is essential.</b> 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>› <b>Distilled water</b> should be used as jar water<sup>2</sup>. 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). <b>After the use of sanitisers, the receptacle must be rinsed carefully with water before the reset of the leeches.</b> The disinfection process has to be documented.</p>

<sup>1</sup>) Medicinal leeches of bbez: Wild cultured leeches and bred leeches for therapeutic use.

<sup>2</sup>) **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)
<b>Light:</b>	No direct sunlight; <i>ideal:</i> dimmed	Dimmed
<b>Temperature:</b>	5 °C up to 18 °C maximum	5 °C up to 8 °C (Fridge <sup>3)</sup> )
<b>Water Change:</b>	Every second day	Weekly
<b>Quantity per litre</b>	Maximum 5 leeches	Maximum 5 leeches
<b>Quantity per receptacle</b>	Maximum 10 leeches of equal size	Maximum 10 leeches of equal size

<sup>3)</sup> 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 intended to removes potential germs from the leech skin.
- › *Treatment site:* Leeches are sensitive to vibrations or odors leading to hesitant or complete reluctance of biting. Avoid nicotine, essential oils, glaring lamplight or thunderstorms.
- › Use only leeches with vital appearance.
- › Apply leeches e.g. using an applicator or a cut plastic syringe.
- › Leeches must not be used a second time! 
- › Leeches used for medical purposes must not be reused. They have to be properly disposed of. We offer the possibility of sending the living leeches back to us. This has to be done via a special return kit which can be purchased in our hirudoshop. The alternative option is discarding the leech after killing it. The humane and preferable way of putting the leech down is freezing it (store for at least 48 hours at -18 °C/0 °F), hereby the leech goes into a state of hibernation as it does in winter, and freezes to death without stress. Alternatively putting it in high-proof alcohol (70 %) will kill the leech. For further proceedings thereafter please read the package leaflet.

Generally, the published version of this document on our website <https://leech.biz/download> (Information on Quality Assurance for the Rearing of Medirud Leeches) applies.



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