

Information on Quality Assurance of Keeping Medirud®Biebertal (bbez Medicinal Leeches) PZN¹ 6904955 (Imported Leeches) und PZN 6904949 (Facility-Bred Leeches) for Therapeutic Use (16.12.2015)

The subsequent quality assurance measures for Medirud®Biebertal are dedicated for maintaining the quality of medicinal leeches for the time span between from leaving the company until the patient's therapeutic use. In case of non-compliance to these standards, a loss of quality of the medicinal leeches might happen associated with an increased risk of adverse events.

Quality Assurance Requirements for the Keeping of Leeches Preceding the Therapeutic Use:

Medicinal leeches are aquatic animals necessitating specific keeping conditions until their therapeutic use. The quality assurance requirements depend on the length of time the leeches are kept before their therapeutic use.

Basic Requirements for Leech Keeping		
<ul style="list-style-type: none"> The transport packaging of medicinal leeches sent by the company bbez is suitable for a storage of maximal 4 days after arrival. Not later than this time span, the leeches should be kept according to the requirements as indicated below. The leeches should be given a shower before the placement into the receptacle (s. 3. Bullet point on the back side of this information paper). 		
<ul style="list-style-type: none"> A tightly sealed receptacle (e.g. jar with screw-cap or clamping fastener). The oxygen content in these receptacles is sufficient for medicinal leeches. The receptacles can be kept unperforated and closed. 		
<ul style="list-style-type: none"> A maximum of 5 medicinal leeches should be kept per one litre of water. No more than 10 medicinal leeches should be kept in one receptacle (Risk Minimisation). 		
<ul style="list-style-type: none"> The receptacle must be cleaned at regular intervals (At fortnightly intervals and at every new insertion of medicinal leeches). Glass jars can be cleaned in a dishwasher. We discourage from the use of sanitizers. 		
<ul style="list-style-type: none"> We recommend to insert some sharp-edged stones on the bottom of the receptacle. The leeches use them when skinning. (The stones should be boiled for disinfection). 		
<ul style="list-style-type: none"> We strongly recommend the use of deionised or distilled water (Battery water or ironing water available at low prices, e.g. in hardware stores). It is essential to add 3 pinches of table salt or sea salt per one litre of water). 		
<ul style="list-style-type: none"> Tap water exceeding water hardness of 3 (hard) or approx. dH 14° is not appropriate 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. Tap water for the keeping of leeches must not be chlorinated. Chlorination of tap water usually is done in Germany in case of the risk of germ contamination. There is the permanent risk of intermittent chlorination of tap water. 		
<ul style="list-style-type: none"> In case of water change, the fresh water temperature should be adjusted to the existing water temperature. 		
<ul style="list-style-type: none"> Concerning the the place of the leech receptacle, any disturbances should be avoided (dazzling light, noise, or vibrations). 		
Specific Keeping Requirements:		
Keeping Conditions	Short-time Keeping (up to 7 days)	Long-term Keeping (more than 8 days)
Light:	Regular daylight or dimmed light, no exposure to sunlight	Dimmed light
Temperature:	4°C (39 °F) to maximum 25°C (77 °F)	8°C (46 °F) to minimum 4°C (39 °F)
Water Change:	Every 3 rd day	Weekly

¹ PZN = Central Pharmaceutical Code; German Drug Identification Number (Pharmazentralnummer; bundeseinheitlicher Identifikationschlüssel für Arzneimittel)

Quality Assurance Measures Immediately Before Therapeutic Application

The following quality assurance measures are recommended immediately before the initiation of medicinal leech therapy:

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| <ul style="list-style-type: none">• The water temperature of the leech receptacle should be adjusted to room temperature at least 2 hours before treatment. |
| <ul style="list-style-type: none">• The place of medicinal leech treatment should be free of any disturbances, as far as possible. In case of thunderstorm, the medicinal leech treatment should be cancelled (Leeches do not bite during thunderstorms). |
| <ul style="list-style-type: none">• To reduce potential medicinal leech skin bacteria, the leeches should be given a shower with running tap water (approx. 25 °C or 77 °F) on a sieve for 3 to 5 minutes. For this process of washing, any tap water is suitable. |
| <ul style="list-style-type: none">• Use only healthy and vital appealing medicinal leeches. |

Leeches are living creatures being very sensitive to insufficient keeping conditions!

For Your Current Notifications: