› allergic reaction to constituents or ingredients of leech saliva (animal proteins)

Very rare (<1/10.000)

› symptoms corresponding to a B cell pseudolymphoma (cited as arthropode reaction in former leech literature), also occurring as long-term sequelae, possibly even years after the leech treatment

› systemic sepsis infections, e.g. via secondary infection of the wound (various possible pathogens) or as a primary infection by aeromonas hydrophila or aeromonas veronii biovar sobria. Antidote: concomitant antibiosis with 3rd generation cephalosporins or gyrase inhibitors

› blood loss requiring blood transfusion

› Anaphylaxis (Grade I-IV). Actions to be taken according to the severity grade in line with the ERC-Guidelines (European Resuscitation Council)

Additional warning

In the course of leech treatment, a transmission of even unknown infectious diseases pathogens cannot be excluded. Our quality control system, especially the 32-weeks quarantine interval, has shown in a microbiological study that after the quarantine none of the examined viruses could be detected in the gastro-intestinal tract of the leeches. Accordingly, the risk of viruses transmission is excluded as far as possible.
As the documentation on complete safety with regard to transmission of infections is still pending, the therapist should consider therapeutic alternatives before applying leech therapy.
Distinct local inflammations associated with the leech treatment of extremities, resembling the clinical picture of erysipelas, phlegmons, or lymph tract inflammations (lymphangitis) are usually not caused by a bacterial infection. They develop generally as local over-reaction to the leech saliva ingredients. Antihistamines (local or oral) are the treatment of choice for these adverse events. To differentiate these symptoms as adverse events or as bacterial infections, CRP laboratory values (C-reactive protein) and leucocytes count should be checked in addition to the clinical signs as basis of the therapist`s decision-making. Additional antibiotic treatment is indicated in case of distinct increases of these laboratory values.

Overdose (Emergency information for therapists)

Check aPTT and other coagulant parameters. Check haemoglobin level and, if necessary, prepare for blood transfusion.

Leech care and keeping

Unpack the leeches immediately upon delivery arrival. The leeches should be kept in a clean receptacle with a tight lid. The receptacle should be filled halfway with clean, unchlorinated water with a low calcium content (e.g. distilled water with 0.5 grams of salt per liter or uncarbonated mineral water) and should be rinsed once every 2 days or when the water becomes murky. Keep the receptacle in a cool, dark place at 5°C to 18°C. Cool storage will reduce the growth of pathogens. It is normal for the leech to shed its slimy coating every 2 to 3 days; to facilitate this, it is recommended to place sharp stones on the bottom of the receptacle. Disinfect the storage receptacles regularly. Disinfection should be recorded in pharmacies or in medical units.

Shelf life

The length of time leeches may be stored depends on the quality of care. When kept as described above (“Leech care and keeping”), the shelf life is 7 days.

Disposal

After therapeutic usage, the leeches must be disposed of. This can be done by sacrifice and disposal of the leeches, or by sending them back to the supplier (possible only for customers in Germany). For the sacrifice of the leeches, freezing at a temperature of -18° C for at least 12 hours or high percentage alcohol (spirits) is appropriate. It is not permitted to release the leeches into the wild. The disposal in Germany should follow the rules as laid out in the disposal regulation 18 01 02 for organs and blood products. In view of the small amount of blood within the leech (5-10 ml), likewise the disposal regulation 18 01 04 can be applied. This regulation refers to “Collection and disposal of waste without particular requirements for prevention of infections (e.g. wound dressings, plaster casts, laundry, disposable clothes, nappies)”.

Small amounts of this waste can also be disposed of in the residual waste/ municipal solid waste by placing the leeches in a watertight, unbreakable receptacle labeled as “Waste originating from human medical treatment”. Please make sure to follow the country-specific and local authority regulations on waste disposal. If you have questions concerning disposal procedures, please contact your local waste disposal authority.

bbez Biebertaler Blutegelzucht

Pharmaceutical Enterprise

Biebertaler Blutegelzucht GmbH
Talweg 31 | D-35444 Biebertal

tel +49 6409 66140-0
fax +49 6409 66140-75
leech@leech.de
www.leech.de

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Package insert for the appropriate use of live medicinal leeches on humans: Wild cultured leeches and bred leeches

Blutegel Medirud®

Read carefully the entire package insert as it contains information and instructions of importance to you. This medicinal product is available without a physician‘s prescription. For the best possible treatment results and to ensure safe application, the medicinal leech must be properly applied by a trained physician or alternative practitioner.

› Keep this package insert handy. You may need to refer to it again at a later date.

› Ask your physician, alternative practitioner or pharmacist if you require further information or advice.

› In case of adverse reactions which are unusual in form or intensity, consult a physician or alternative practitioner immediately.

› If any of the listed adverse reactions causes serious impairment or if you notice adverse reactions which are not listed in the package insert, please inform your physician, alternative practitioner or pharmacist.

Leeches for medical application are a finished medicinal product according to § 2 Para. 1 No. 1 German Medicinal Products Act.

What are medicinal leeches and what is their use in medicine?

Term:	Medicinal leeches Wild cultured leeches and bred leeches
Active ingredients:	Polypeptides and enzymes Main active ingredient: hirudin
Composition:	Biting and suction device capable of releasing active ingredients into blood and tissue
Form of presentation:	Living organism weighing 0,5 to 5 grams for intra cutaneous application. The effect results from the interaction of the release of the active ingredients when biting and bloodletting during the approximately 30 to 90 minutes sucking procedure
Therapeutic effects:	Haemodilution, suppression of inflammation, blood letting, lymph flow acceleration, relief from pain

Indications with number of leeches per application

Range of Indications		Leeches
Adnexitis, Parametritis	Abdominal inflammation in women	4 - 6
Angina pectoris	Chest pain caused by ischaemic coronary congestion	4 - 6
Apoplexy	Stroke	4 - 6
Arthritis	Acute and chronic joint inflammation	4 - 8
Osteoarthritis Gonarthrosis, Rhizarthrosis	Degenerative joint disease: knee and thumb arthritis	4 - 8
Cephalgia	Headache	4 - 6
Cholezystitis	Gall bladder inflammation	4 - 6
Epicondylitis humeri radialis	Tennis elbow	4 - 6
Furuncles and carbuncles	Furuncles and carbuncles	3 - 6
Haematoma	Bruise	4 - 6
Haemorrhoids	Haemorrhoids	3 - 4
Herpes zoster	Shingles	4x 4 - 6
Hypertension	High blood pressure	3 - 6
Hyperuricaemia	Gout	6 - 8
Lumbar spine syndrome	Low back pain	4 - 7

Range of Indications		Leeches
Microangiopathy	Circulatory disorders of the capillaries	2 - 6
Myotendinosis / Myogelosis	Muscle tension / muscle stiffness	4 - 8
Orchitis	Inflammation of the testicles	4 - 6
Otitis media	Inflammation of the middle ear	2
Patellar tendon syndrome	Overstraining of the knee cap (Jumper`s knee)	4 - 6
Phlebitis / Thrombophlebitis	Inflammation of the veins	2 - 6
Plastic and reconstructive surgery	Graft skin and tissue reconstruction in plastic surgery	4 - 6
Rheumatism	Rheumatism (Dosage depending on affected region)	
Tendovaginitis	Inflammation of the tendon and its surrounding sheath	4 - 6
Tinnitus	Ears ringing or similar sounds	2
Tonsillar abscess	Tonsillar abscess	4 - 6
Ulcus cruris	Leg ulcer	4 - 6
Varicosis	Varicose veins	4 - 8

The range of indications is based on clinical studies (underlined) as well as on case studies in medical publications (Müller „Handbuch der Blutegeltherapie“; Michalsen/Roth „Medicinal Leech Therapy“; Kaehler Schweizer/Westendorff „Hirudotherapie“)

Mode and duration of administration:

The mode and duration of administration is determined by the specific indications (see also “Range of Indications”).

What must be considered before, during, and after application?

› It is recommended that haemoglobin is checked prior to leech treatment (preferentially within the last 2 months).

› Use only leeches which appear to be healthy. In a normal state, the leech will appear lively and shows no external signs of injury or constrictions of its body. Signs of leech diseases might appear as traces of blood, foul smell, limpness, pale or yellowish skin colour, seemingly oily body segments, hard spots, knots, constrictions, swollen head, sores, pustules, reddened lips of the anterior sucker, and a slimy, whitish coating.

› Prior to application, rinse off the leech with lukewarm water to remove pathogens from the surface of the skin.

› Leeches will bite only reluctantly or not at all when in the proximity of nicotine or essential oils, during thunderstorms, when exposed to strong artificial light, and when applied by an overly nervous user.

› The number of leeches to be applied depends on the indication. No more than 10 leeches should be applied at any one time to a normal, healthy person.

› Pharmaceutical products containing acetylsalicylic acid, high dosages of enzyme preparations, high dosages of fish oil as well as vitamin C infusions must not be taken in the three days prior to leech application and may not be taken for 2 days following the treatment.

› The therapist must make an individual decision concerning a supplemental antibiotic treatment for higher-risk patients before the start of therapy.

› When leeches are used in cases of surgical indication or when treating a patient with immune system deficiency (see “Contraindications”), a supplemental antibiosis with 3rd generation cephalosporins or gyrase inhibitors is recommended.

› When treating patients suffering from an immune system disease, an experienced physician specialised in the treatment of such diseases has to be consulted.

› Cleansing of the site of the bite must be done with water and curd soap exclusively.

› The leech should be placed on the skin of the patient either by turning a jar upside down onto the skin or by using a cut off plastic syringe. In the proximity of a body orifice, there is the risk of the leech moving inside. This can be prevented by placing a receptacle over the leech until the leech is fixed by initiating the biting and sucking process.

› The leech should not be forcibly removed while sucking. In order to keep the risk of infection to a minimum, the leech should be allowed to drop off by itself. To prevent leakage of intestinal content, the leech should not be squeezed or sprinkled with a saline solution nor brought into contact with any other solution which may cause vomiting.

› The site of the bite should be covered with sterile bandaging. As the subsequent blood oozing can last from 12 to 24 hours, be sure to apply adequate absorbent material (a compression bandage should not be used). After the cessation of bleeding, the wound should be covered with an adhesive bandage for another 48 hours. During this period, the site of the bite should not be subject to washing, bathing or showering.

› If leech application is carried out on an extremity, the treated extremity should be kept in a raised position to avoid strong swelling of the treated area.

› To avoid subsequent infection of the wound, scratching of the wound has to be avoided, even if, as it is frequently the case, the wound itches badly. If necessary, an anti-itching ointment or gel may be applied and the wound should be covered with an adhesive bandage.

› Should it be necessary to terminate treatment prematurely, use a sterile spatula for the release of the sucker cup to remove the leech.

› A leech may never be used a second time.

Contraindications:

When should medicinal leeches not be used?

Medicinal leeches must not be used in cases of

› inherited or acquired bleeding disorders (haemophilia)

› anaemia or bone marrow suppression

› concomitant treatment with haemodilution inducers (oral and non-oral anticoagulant substances such as cumarin, phenprocoumon or clopidogrel type, direct or new oral anticoagulants such as NOACs/DOACs, platelet aggregation inhibitors for the prevention thrombosis, embolism and stroke). Exception: acetylsalicylic acid at daily doses up to 100 mg.

› erosive gastritis, gastrointestinal bleeding, or stomach ulcers tending to bleed

› infectious diseases during an acute stage or with fever

› serious, instable organ diseases

› artificially induced (e.g. by medication) suppression of immune reactions

› pronounced allergy diathesis and specific protein allergies

› known allergies to leech constituents, or one of the ingredients in leech saliva

› tendency to bleed (haemorrhage diathesis)

› general and local wound healing disorders

› excessive formation of scar tissue (keloid formation)

What must be taken into consideration in cases of pregnancy and during lactation?

In general, no blood should be drawn during pregnancy. It must be considered that unwanted adverse reactions to leech therapy might occur, necessitating the treatment with medication which is not permitted during pregnancy.

What should be taken into consideration when treating children?

For the leech treatment of children and adolescents, a physician or alternative practitioner should be consulted, since experience with this patient group is to date inadequate for any general recommendations.

Interactions with other medicinal products: Which other medicinal products have an influence on the efficacy of medicinal leeches or which medicinal products` efficacy would be affected by medicinal leeches?

Up to now, no interactions are known.

Adverse events:

Very frequent (>1/10)

› localised bite pain for 1 to 5 minutes, usually described as slightly painful

› swelling of the edges of the three-cornered wound, usually lasting 12 to 48 hours accompanied by a localised feeling of tension

› localised itching for several hours after treatment, lasting 2 to 3 days

› red-violet colouring of the edges at the site of the bite, later turning yellowish, lasting about 14 days

› regional swelling of the lymph nodes

Frequent (>1/100)

› heavy secondary haemorrhage accompanied by a decrease in haemoglobin

› a strictly localised inflammation with partially papular swelling of the site of the bite, often accompanied by itching

› local allergic reactions

› swelling of the area surrounding the site of the bite on extremities, lasting several days

Occasional (>1/1.000)

› severe decrease of blood pressure (circulatory depression and vasovagal reaction)

Rare (>1/10.000)

› distinct localised inflammation such as erysipelas, phlegmon, lymphangitis. Antidote: 3rd generation cephalosporins or gyrase inhibitors (Please refer to the statements on distinct local inflammations in the section “Additional Warning”)