

What are medicinal leeches and for what are they used?

Term:	Medicinal leeches Bred and cultivated leeches for therapeutic applications on humans.
Active ingredients:	Polypeptides and enzymes. Main active ingredient: hirudin
Composition:	Biting and suction apparatus capable of releasing active ingredients into blood and tissue.
Form of presentation:	Living organism weighing 1 to 5 grams for intracutaneous application. The effect results from the interaction of the release of the active ingredients when biting and bloodletting during the approximately 30 to 60 minute sucking procedure.
Therapeutic effects:	hemodilution, suppression of inflammation, blood letting, lymph flow acceleration, relief from pain.

Applications:

Indication	Dosage (number of leeches per treatment)	Indication	Dosage (number of leeches per treatment)
adnexitis parametritis	abdominal inflammations in women 4 - 6	microangiopathy	circulatory disorder of the capillaries 2 - 6
angina pectoris	chest pain caused by ischemia of the heart muscle 4 - 6	myotendinous junction / myogelose	muscle tension, hardening of the muscles 4 - 8
apoplexy	stroke 4 - 6	orchitis	inflammation of the testes 4 - 6
arthritis	acute and chronic inflammation of the joints 4 - 8	<u>otitis media</u>	inflammation of the middle ear 2
arthrosis: <u>gonarthrosis</u> and <u>rhi-zarthrosis</u>	degenerative joint disease: knee and thumb arthrosis 4 - 8	patellar tendon syndrome	overstraining of the kneecap (jumper's knee) 4 - 6
cephalgia	headache 4 - 6	phlebitis / thrombophlebitis	inflammation of the veins 2 - 6
cholecystitis	inflammation of the gall bladder 4 - 6	plastic and reconstructive surgery	graft skin and tissue restoration in plastic surgery 2 - 6
<u>epicondylitis humeri radialis</u>	tennis elbow 4 - 6	rheumatism	rheumatism (dosage dependent on affected region)
furuncles and carbuncles	furuncles and carbuncles 3 - 6	tendovaginitis	inflammation of the tendon and its surrounding sheath 4 - 6
hematoma	bruise 4 - 6	tinnitus	ringing or similar sound in the ears 2
hemorrhoids	hemorrhoids 3 - 4	tonsillar abscess	tonsillar abscess 4 - 6
herpes zoster	shingles 4x4 - 6	ulcus cruris	leg ulcer 4 - 6
hypertension	high blood pressure 3 - 6	varicosis	varicose veins 4 - 8
hyperuricaemia	gout 6 - 8		

The areas of application are based on clinical studies (underlined) as well as on case studies in medical publications. (based on: Müller "Handbuch der Blutegeltherapie" and Michalsen/Roth/Dobos "Medicinal Leech Therapy")

Pharmaceutical Enterprise



Manufacturing authorisation for ingredients of animal origin (leeches), human and veterinary medicinal products in according to Art. 40 and Art. 111 (1) of Directive 2001/83/EC transposed in the following national legislation: Sect 13 para 1 German Drug law (Arzneimittelgesetz - AMG)

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Pharmaceutical Product: Medirud®Biebertal

(medicinal leeches: hirudo medicinalis/vervana/orientalis)

Bred and cultivated leeches for therapeutic applications on humans

Package insert (information for the user) for proper application and use on humans of live medicinal leeches: Cultivated leeches (leeches harvested in the wild and kept in cultivation for 32 weeks) and facility-bred leeches

(dated 01 November 2011)

Leeches for medical applications are a finished medicinal product as defined in section 2 para 1 no. 1 and section 4 para 1 of the German Drug Law

Carefully read the entire package insert as it contains information and instructions of importance to you. This medicinal product is also 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 nonmedical practitioner.

- Keep this package insert handy. You may need to refer to it again at a later date.
- Ask your physician, nonmedical practitioner or pharmacist if you require further information or advice.
- In case of side effects which are unusual in form or intensity, consult a physician or nonmedical practitioner immediately.
- If any of the listed side effects causes you serious impairment or if you notice side effects which are not listed in the package insert, please inform your physician, nonmedical practitioner or pharmacist.

Highly sensitive – hygienic – reliable suction
Medicinal leeches from Biebertal

Mode and Duration of Administration:

The mode and duration of administration is to be determined by the specific indications (see also "Areas of Application").

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

- It is recommended that hemoglobin be checked prior to leech treatment (if possible within the last 2 months).
- Use only leeches which appear to be healthy. In a normal state, the leech will appear lively and show no external signs of injury or constrictions of its body. Possible signs of leech diseases: traces of blood, foul smell, limpness, pale or yellowish skin color, 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 indications. 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 applying therapist must individually make a decision concerning a supplemental antibiotic treatment for higher-risk patients before the therapy begins.
- When used in cases of surgical indication or when treatment of a patient with immune system deficiency (see "Contraindications") is necessary, then a supplemental antibiotics with 3rd generation cephalosporins or gyrase inhibitors is recommended.
- When treating patients suffering from a disease of the immune system, an experienced physician specializing in the treatment of such diseases is to be consulted.
- Cleansing of the site of the bite is to be done with curd soap and water only.
- The leech should be placed on the skin either by turning a receptacle upside down onto the skin or by using a blunted plastic syringe. In the proximity of a bodily orifice, it is possible the leech may move toward it. This can be prevented by placing a receptacle over the leech to keep it from moving.
- The leech should not be forcibly removed while it is sucking. In order to keep the risk of infection to a minimum, the leech should be allowed to drop off of its own accord. To prevent leakage of intestinal content, the leech should not be squeezed or wetted with a saline solution nor brought into contact with any other solution which may cause regurgitation.
- The site of the bite should be covered with sterile bandaging. As the subsequent bleeding can last anywhere from 12 to 24 hours, be sure to apply adequate absorbent material (a compression bandage is normally not to be used). After 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 subjected to washing, bathing or showering.
- If leech application is carried out on an extremity, the said extremity should be kept in a raised position to avoid strong swelling of the treated area.
- To avoid later infection of the wound, scratching of the wound is to be avoided, even if, as 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 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 (hemophilia)
- concomitant treatment with anticoagulant substances which cause the quick or INR values (coagulant values) to sink substantially (e.g. coumarin, phenprocoumon or clopidogrel)
- anemia or bone marrow suppression
- erosive gastritis, gastrointestinal bleeding or stomach ulcers tending to bleed
- infectious diseases during an acute stage or with fever
- serious, instable diseases of an organ
- artificially induced (e.g. by medication) suppression of immune reactions or pronounced allergy diathesis and specific protein allergies
- known allergies, such as to one of the ingredients in leech saliva
- tendency to bleed (hemorrhage diathesis)
- general and local wound healing disorders
- excessive formation of scar tissue (keloid)

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

No blood should be drawn during pregnancy. If unwanted side effects occur, treatment with medication not permitted during pregnancy could become necessary.

What should be taken into consideration when treating children?

For applications involving children and youths with a weight of 30 kilograms or less, a physician or nonmedical practitioner should be consulted, as experience with this group is to date inadequate for making any general recommendations.

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

Up to now, no interactions are known.

Side Effects:

Very frequent (>1/10)

- localized pain of 1 to 5 minutes, normally described as slightly painful
- swelling of the edges of the three-cornered wound, normally lasting 12 to 48 hours accompanied by a localized feeling of pressure
- localized itching after several hours lasting 2 to 3 days after treatment
- red-violet coloring of the edges of the site of the bite, later turning yellowish, lasting for about 14 days
- regional swelling of the lymph nodes

Frequent (>1/100)

- heavy post-application bleeding accompanied by a decrease in hemoglobin
- a strictly localized inflammation with partially papular swelling of the site of the bite, often accompanied by itching
- local allergic symptoms
- swelling of the area surrounding the site of the bite on extremities, lasting a number of days

Occasional (>1/1000)

- severe sinking of blood pressure (circulatory depression and vasovagal reaction)

Rare (>1/10000)

- distinct localized inflammation such as erysipelas, lymphangitis. Antidote: 3rd generation cephalosporins or gyrase inhibitors

Very rare (<1/10000)

- symptoms corresponding to an arthropod reaction
- systemic sepsis infections, for example through secondary infection of the wound (various possible pathogens) or through a primary infection by aeromonas hydrophila or aeromonas veronii biovar sobria. Antidote: concomitant antibiotics with 3rd generation cephalosporins or gyrase inhibitors
- loss of blood requiring transfusion

Additional Warning

The possibility of transmission of an infectious disease during leech therapy, including diseases of an unknown nature, cannot be totally discounted, especially in the case of medicinal leeches harvested in the wild. Through our quality control system, especially the 32-week-quarantine for such leeches, this as yet unproven risk is reduced as much as possible. As the documentation concerning sufficient safety with regard to transmission of infections has yet to be presented, the therapist should consider therapeutic alternatives before applying leech therapy (see "Applications").

Overdose (Emergency information for therapists)

Check aPTT and other coagulant parameters. Check hemoglobin 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 (for example, 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 between 5°C and 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 accordingly in pharmacies or in medical units.

Storage 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 storage life is 7 days. If kept in the delivery container at 5°C to 18°C, the storage life is 1 day.

Disposal

After usage, the leeches must be disposed of. For this purpose, two methods have proven useful: using high percentage alcohol (spirits) or freezing at a temperature of -18°C for at least 12 hours. It is not permitted to release the leeches into the wild. Disposal should adhere as closely as possible to the rules, regulations and recommendations as laid out in disposal regulation 18 01 02 for organs and blood products. If you do not have access to appropriate commercial disposal, then dispose of the leeches in unsorted mixed refuse, placing the leeches in a watertight, unbreakable receptacle labeled as medical refuse. If you have questions concerning disposal procedures, please contact your local waste disposal authority, as waste disposal restrictions and requirements vary greatly from place to place.