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Important information. Read carefully!

Cerebrolysin®

1ml, 5ml and 10ml ampoules/30ml, 50ml vials

For the modern, safe and effective treatment of disturbed cerebral functions

Composition

Cerebrolysin® is a peptide preparation. The solution, ready for injection or infusion, is free of proteins, lipids and antigenic properties. 1ml of Cerebrolysin® contains 215.2mg Cerebrolysin® concentrate as active ingredient in aqueous solution.

Route of administration

Solution for intramuscular and intravenous injection or intravenous infusion.

Pharmacodynamics

The efficacy of Cerebrolysin® is proven in numerous animal experiments and clinical trials. Cerebrolysin® is a brain-specific peptidergic nootropic and neurotrophic drug able to affect the central nervous system in a multimodal way. This multimodal action of Cerebrolysin® expresses itself as: *1) regulation and improvement of the neuronal metabolism* which prevents lactacidoses in hypoxic or ischaemic episodes, *2) modulation of the synaptic plasticity* which corresponds to an improvement of behaviour and learning capacity, and *3) a completely unique neurotrophic effect,* inducing neuronal differentiation, guaranteeing full neuronal function and protection against different types of ischaemic and neurotoxic lesions.
In *controlled clinical trials* Cerebrolysin® treatment leads to an improvement in the cognitive performance and mood of patients suffering from *Alzheimer's disease.* Therefore, the amount of care needed by these sufferers decreases. In these patients marked improvement is observed in 61.7% of the Cerebrolysin®-treated group (as assessed by the Clinical Global Impressions scale CGI). Another clinical trial in patients with *vascular dementia* demonstrates enhancement of memory performance in the group receiving Cerebrolysin® treatment. An improvement in the global clinical picture is also noticed in this illness. A further study involving patients from nine different disease entities establishes the effectiveness of Cerebrolysin® through the use of 11 psychological tests subjected to a variance analysis. After *stroke and craniocerebral trauma* treatment with Cerebrolysin® leads to an accelerated recovery. Literature on Cerebrolysin® is available upon request.

Pharmacokinetics

Cerebrolysin® passes through the blood-brain barrier. Up to eight hours after iv administration of Cerebrolysin® neurotrophic activity can be detected in the human serum, indicating long-lasting effects even after a single iv administration.

Toxicological properties

Cerebrolysin® is generally well tolerated and possesses an extremely high margin of safety. In human therapeutic dosages this drug produces almost no toxic symptoms. The toxicological data are listed below.
Acute toxicity: after a single iv administration of Cerebrolysin® the following LD_{50} values were observed (14 days observation period): male rats 68ml/kg body weight, female rats 74ml/kg body weight; dogs, male and female, >52.2ml/kg body weight. *Chronic toxicity (multiple doses over six months):* rats received up to 12.5ml/kg body weight daily for 26 weeks: only moderate changes in the blood count were observed; dogs: the highest administered doses were 9ml/kg body weight daily for 28 days (about 10 times the human therapeutic dosage) and 4.5ml/kg body weight daily for 26 weeks (about five times the human therapeutic dosage): no systemic substance-dependent intolerance reactions were observed.
Reproductive toxicity: Cerebrolysin® was injected iv to the dams at the highest possible volumes: in no case was an alteration of the gestagenic period observed, neither in rats nor in rabbits. Neither embryotoxic nor teratogenic effects nor impairments of embryonic or neonatal developments were found; no influence on the progeny (F_1 and F_2 generations) was evident. No influence on the fertility and the reproductive performance of the parent animals was observed. *Mutagenicity, sensitising effect and carcinogenicity:* Cerebrolysin® does not show any mutagenic potential, sensitising effect or carcinogenicity in toxicological tests, neither in vitro nor in vivo.

Indications

- disturbances of concentration and memory
- degenerative dementias, including Alzheimer's disease
- vascular dementias, eg multi-infarct dementia
- mixed forms of dementia (degenerative and vascular contribution)
- sequels of stroke (ischaemic and haemorrhagic)
- posttraumatic or postoperative complaints, eg following cerebral contusion, concussion or neurosurgical operation.

Contraindications

- hypersensitivity to one of the components of the drug
- status epilepticus or grand mal convulsions; an increase in the seizure frequency may be seen in these cases
- severe impairments of renal function.

Side effects

Cerebrolysin® is generally well tolerated. If injected too fast it may cause a moderate heat sensation. In extremely rare cases a hypersensitivity reaction manifested itself as chills, headaches or as slight increases in body temperature, the cause of which is probably the hyperresponsiveness of the patient. In no case to date has the undesirable effect persisted or proved threatening to the patient.

Warnings and precautionary measures

Patients with severe renal impairment must be excluded from a Cerebrolysin® therapy. Animal experimental data did not show any evidence of teratogenic effects. There is no clinical experience with Cerebrolysin® in pregnant women. Therefore, unless the potential benefits outweigh any potential risk, Cerebrolysin® should not be administered during pregnancy and the lactation period.

Interactions

The concomitant administration of Cerebrolysin® with antidepressive drugs or MAO inhibitors can lead to cumulative effects. In these cases a dose reduction of the antidepressive drug is advisable.

Dosage and administration

Cerebrolysin® is available in 1ml, 5ml and 10ml ampoules and in vials of 30ml and 50ml. Up to 5ml per intramuscular administration, for administrations over 5ml an intravenous injection or infusion is advised. Cerebrolysin® can also be given diluted in a standard iv solution (eg physiological saline solution, Ringer's solution, glucose 5%, dextran 40) infused slowly over approximately 20 to 60 minutes. Once daily applications of Cerebrolysin® for a minimum of 10 to 20 days are recommended. This constitutes a course of therapy. In mild cases 1–5ml, in severe cases 10–30ml should be applied. The length of the therapy and the individual doses depends on the age of the patient as well as on the severity of the disease. Usually a treatment period of three to four weeks is recommended. Therapy courses can be repeated several times in accordance with the clinical picture of the patient until no further improvement can be observed. Therapy-free intervals should be maintained between courses. In severe cases it is advisable not to interrupt treatment abruptly but to continue with one injection every other day for a period of four weeks.
From the above mentioned clinical trials the following daily dosage guidelines for adults can be deducted: in dementias 5–30ml daily, in postapoplectic deficits and brain injuries 10–50ml daily.

Presentation and packs

Original packs with	10 ampoules of	1ml
Original packs with	5 ampoules of	5ml
Original packs with	5 ampoules of	10ml
Original packs with	5 vials of	30ml
Original packs with	5 vials of	50ml

Storage

Keep in a safe place out of the reach of children.
Store at room temperature not over 25°C, away from light.

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