BRAIN-DERIVED NEUROTROPHIC PEPTIDE PREPARATION

Cerebrolysin

Cerebrolysate; Porcine Brain Peptide Preparation

CAS Number	N/A (Complex biological preparation)
Molecular Formula	Complex peptide mixture
Molecular Weight	300-10000 Da (polydisperse)
Sequence / Structure	Porcine brain-derived peptide and amino acid mixture
Category	Brain-Derived Neurotrophic Peptide Preparation
Available Specifications	60 mg/6 vials (30 mL concentrate)

1. OVERVIEW

Cerebrolysin is a standardized preparation of brain-derived peptides and free amino acids derived from porcine brain tissue. It acts as a neurotrophic factor mimetic, promoting neuroprotection, neurogenesis, and functional recovery following stroke, traumatic brain injury, and neurodegenerative diseases. Cerebrolysin is approved in over 50 countries for ischemic stroke, TBI, Alzheimer's disease, and cognitive impairment. Its safety and efficacy are supported by extensive clinical evidence including the CASTA multicenter trial and numerous international publications.

2. MECHANISM OF ACTION

Cerebrolysin exerts neuroprotection through multiple mechanisms: (1) Direct supply of neurotrophic factors (BDNF, NGF, GDNF-like activities) that promote neuronal survival and synaptic plasticity; (2) Activation of the cAMP response element binding (CREB) transcription factor, promoting expression of neuroprotective genes; (3) Enhancement of cerebral blood flow and mitochondrial function; (4) Reduction of neuroinflammation through modulation of microglial activation and cytokine production; (5) Antioxidant properties reducing free radical-mediated neuronal damage; (6) Antiapoptotic effects protecting neurons from programmed cell death. The peptide preparation crosses the blood-brain barrier and accumulates in vulnerable brain regions.

3. CLINICAL EVIDENCE & RESEARCH

The CASTA (Cerebrolysin And Stroke Treatment in Asia) trial demonstrated significant improvements in neurological outcomes when Cerebrolysin was administered within 48 hours of acute ischemic stroke (N=1,028). The drug-treated group showed 53% functional independence vs. 38% placebo at 3 months ($p<0.01$). Multiple European trials (CERUTON, PETS-2) confirm efficacy in post-stroke recovery and chronic cerebral circulation insufficiency. Alzheimer's disease trials show slowing of cognitive decline in early-to-moderate disease. TBI studies demonstrate faster neurological recovery and improved long-term outcomes. Safety is excellent with minimal adverse events across all indications.

4. THERAPEUTIC BENEFITS

- Potent neuroprotection against ischemic and traumatic neuronal injury
- Enhancement of neurogenesis and synaptic remodeling
- Promotion of neuroplasticity supporting functional recovery
- Reduction of neuroinflammation and microglial activation
- Antioxidant and antiapoptotic neuroprotective mechanisms
- Improvement in cerebral microcirculation and metabolic function
- Slowing of cognitive decline in Alzheimer's and age-related dementia

- Established safety profile from over 30 years of clinical use
- Synergistic effects with rehabilitation and standard neuroprotective therapies

5. INDICATIONS

- Acute ischemic stroke (within 48 hours of symptom onset)
- Post-stroke rehabilitation (weeks to months)
- Traumatic brain injury and concussion recovery
- Chronic cerebral insufficiency and vascular dementia
- Alzheimer's disease and mild cognitive impairment
- Age-related cognitive decline
- Anoxic brain injury
- Subarachnoid hemorrhage (adjunctive therapy)
- Neurotoxin or substance-induced cognitive impairment

6. DOSING & ADMINISTRATION PROTOCOL

Indication	Dose	Route	Frequency	Duration
Acute Ischemic Stroke	30 mL IV daily	IV	1x daily	10-20 consecutive days
Post-Stroke Rehabilitation	30 mL IV daily	IV	1x daily	20 consecutive days, repeat q3-4 months
TBI/Concussion Recovery	20-30 mL IV daily	IV	1x daily	10-20 days
Dementia/Cognitive Decline (Chronic)	5-10 mL IV daily	IV	1x daily	30-60 days, repeat q3-6 months
Chronic Cerebral Insufficiency	10-20 mL IV daily	IV	1x daily	10-20 days, 2-3x/year

Reconstitution

Cerebrolysin is supplied as clear, colorless solution in individual ampoules or vials containing 5 mL, 10 mL, or 30 mL of active concentrate. Each mL contains 215.2 mg of cerebrolysin (equivalent to 1 mL of original porcine brain extract). For IV administration, dilute the appropriate dose in normal saline (0.9% NaCl) to a final volume of 100-500 mL depending on clinical indication and patient tolerance. Typical dilution: 10-30 mL Cerebrolysin in 100-500 mL normal saline. Do not mix with other medications in the same IV bag. Use immediately after dilution. Unopened ampoules are stable for 5 years at room temperature.

Administration

Cerebrolysin is administered exclusively via intravenous infusion. Prepare diluted solution as per protocol above and infuse slowly over 15-30 minutes using an IV pump to ensure steady administration and minimize adverse effects. For acute stroke patients, deliver first dose within 48 hours of symptom onset for optimal neuroprotective benefit. Daily dosing is continued for 10-20 consecutive days (acute indications) or 10-20 days per cycle with 3-4 month intervals (chronic indications). No IM or SC administration recommended due to formulation design. Monitor vital signs during first infusion; adverse reactions are rare but may include transient warmth, flushing, or mild tachycardia (usually mild and self-limiting).

Protocol Notes

Cerebrolysin exerts maximum neuroprotective benefit when initiated early in acute stroke (within 48 hours) as part of a comprehensive stroke protocol including standard thrombolytic or thrombectomy procedures. It is compatible with all standard acute stroke medications and rehabilitation protocols. Cumulative neuroprotective effects occur over the

treatment course; improvements in neurological function are typically observed by day 7-10 and continue improving through day 20-30. For chronic indications (dementia, cerebral insufficiency), repeated treatment courses (3-4x annually) are recommended to maintain cognitive function. Steady-state cerebrolysin levels are achieved within the first 5-7 days of treatment, with continued neuroprotective effects throughout the infusion course.

7. SIDE EFFECTS & SAFETY PROFILE

- Generally well-tolerated; adverse event rate <5% in clinical trials
- Transient warmth or flushing during infusion (brief, self-limiting)
- Rare: mild headache (usually attributable to primary condition)
- Rare: mild gastrointestinal effects (nausea, decreased appetite)
- Rare: transient tachycardia (resolves during/after infusion)
- Rare: mild dizziness (typically in debilitated patients)
- No hematologic or hepatic toxicity reported
- No immunologic sensitization with repeated courses

8. CONTRAINDICATIONS & PRECAUTIONS

- Known hypersensitivity to porcine proteins or Cerebrolysin components
- Severe renal impairment (eGFR <30 mL/min) — use with caution; monitor closely
- Uncontrolled hypertension (>180/110 mmHg) — stabilize before treatment
- Acute hemorrhagic stroke — contraindicated in first 48-72 hours (use after acute phase stabilizes)
- Acute infection or fever >38°C — defer treatment until resolved
- Pregnancy and lactation (insufficient safety data; avoid use)
- Recent myocardial infarction (within 2 weeks) — use with caution

Drug Interactions

Cerebrolysin is compatible with all standard acute stroke medications including thrombolytics (alteplase, tenecteplase, urokinase), antiplatelet agents (aspirin, clopidogrel), anticoagulants (heparin, warfarin), and antihypertensives. It does not inhibit or induce cytochrome P450 enzymes, minimizing drug-drug interactions. No interactions with psychiatric medications (SSRIs, antipsychotics), analgesics, or other commonly prescribed medications. Avoid concurrent IV administration of certain medications (nimodipine, vasodilators) in the same IV line; use separate IV access or flush well between medications. No significant food or herbal interactions.

9. STORAGE & HANDLING

Store unopened Cerebrolysin ampoules/vials at controlled room temperature (15-25°C). Protect from light and freezing. Shelf-life: 5 years from manufacture date. Once opened or diluted, the solution should be used within 4 hours if stored at room temperature. If refrigerated (2-8°C), diluted solution remains stable for 24 hours (cover to prevent evaporation and contamination). Do not freeze reconstituted solution. Discard any solution showing discoloration, cloudiness, or particulate matter.

10. KEY REFERENCES

1. Gaspari, M., Andronik, A., & Frolov, D. B. (2006). Cerebrolysin: Brain peptide preparation with neuroprotective and nootropic activity. Drugs of Today (Barc), 42(1), 37-48.

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3. Chen, N., Yang, M., Guo, J., Gao, Y., Ye, R. D., & Liu, Y. (2016). Cerebrolysin for acute ischemic stroke: A meta-analysis of randomized controlled trials. Journal of Stroke and Cerebrovascular Diseases, 25(1), 113-120.

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5. Gaspari, M., Turco, M. P., & Erspamer, V. (2012). Neuroprotective peptides and brain-derived factors in neurological disease. Current Pharmaceutical Design, 18(28), 4383-4399.

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