CEREBROCIP Injection (Cerebroprotein hydrolysate)

Composition

Each vial contains:
Cerebroprotein Hydrolysate 2100 mg (Approximately) equivalent to
Nitrogen................................. 60 mg
Excipients ............................. q.s.

Dosage Form

Lyophilized powder for Injection.

Pharmacology

Mode of Action

It is reported that cerebroprotein hydrolysate is a unique nutriment for the brain. It helps the central nervous system (CNS) in multiple ways, regulating and improving nerve cell metabolism, promoting synapse generation, inducing nerve cell differentiation, protecting nerve cells against damages by ischaemia and neurotoxins, etc. Animal experiments testified that cerebroprotein hydrolysate promotes cerebral development in chicks, which can also enhance protein synthesis, potentiate functions of the respiratory chain and stimulate the related hormone production in neural cells. Pre-injection of cerebroprotein hydrolysate improves hypoxia tolerability in rats, which depends on the nucleotide concentration in the brain. After administration of cerebroprotein hydrolysate, a pronounced acceleration in maturation in the brain of several day-old rats was demonstrated by electro-optical means and adult rats exhibited enhanced learning ability in labyrinth tests. Compared with a control group, glucose transporter-1 (GLUT-1) in the blood-brain barrier accelerates significantly in rats that were administered cerebroprotein hydrolysate injection.

Cerebroprotein hydrolysate-augmented proliferation, differentiation and migration of adult sub ventricular zone (SVZ) neural progenitor cells results in an increased number of neural progenitor cells and neuroblasts to contribute to neurogenesis. This may be the mechanism for a beneficial effect in acute ischaemic stroke and traumatic brain injury. Enhancement of neuronal survival is produced through an effect on calpain. The hyper-activation of calpain is implicated in a number of neurodegenerative disorders. Calpain is inhibited by cerebroprotein hydrolysate.

A neuromodulatory effect is produced by increasing GLUT-1 expression, which is responsible for more than 90% of glucose transport to the brain. Neuronal plasticity is produced by the reduction of amyloid-beta accumulation, increased MAP-2 and synaptophysin synthesis. Neuro-immunotrophic activity is produced by inhibition of microglial activation and expression of IL-1-beta. This results in reduction of inflammation. Other neurotrophic drugs and nootropics do not have such a broad spectrum of action as possessed by
cerebroprotein hydrolysate. Patients with neurodegenerative disorders can now be managed in a better way with the use of cerebroprotein hydrolysate.

### Pharmacokinetics

The animal brain-derived proteolytic peptide fraction consists of short biological peptides similar or identical to those produced endogenously. Direct measurement of pharmacokinetic properties has not successfully been performed.

Indirect pharmacokinetic data has been established but it is based on the cerebroprotein hydrolysate pharmacodynamic profile. Accordingly, the neurotrophic activity of cerebroprotein hydrolysate can be detected in blood plasma up to 24 hours after a single application. Furthermore, the components of cerebroprotein hydrolysate can cross the blood-brain barrier. Preclinical in vivo experiments revealed identical pharmacodynamic actions on the CNS following intra-cerebroventricular or peripheral application. Thus, indirect evidence for the passage of components of the drug across the blood-brain barrier has been established.

### Indications

For amelioration of cranial injury, cerebrovascular pathological sequelae and aprosexia in dementia.

### Dosage And Administration

Recommended treatment is 10 to 20 days of continuous daily usage of the required dosage of cerebroprotein hydrolysate, based on the patient's age and illness. The usual dosage is 60 to 180 mg of cerebroprotein hydrolysate (calculated by total nitrogen). For preparing the infusion, the first required dose of cerebroprotein hydrolysate should be dissolved in 10 ml of sterile Water for Injection, which can be further diluted in 250 ml of normal saline.

It is further recommended that cerebroprotein hydrolysate (60 to 180 mg) should be slowly perfused in 250 ml of saline within 60 to 120 minutes. Each treatment period consists of ten to twenty times of perfusion according to clinical need.

In severe cases, especially when accompanied with insufficient cerebral vascular compensation, 60 to 180 mg (calculated by total nitrogen) of cerebroprotein hydrolysate can be prepared as an infusion in 250 ml of saline (as detailed above) and intravenously perfused. If given daily, each treatment cycle takes ten to twenty times of continuous perfusion. Cerebroprotein hydrolysate can be used in a combination with other required medications (refer to WARNINGS AND PRECAUTIONS, Drug Interactions), but any mixed injections are not allowed.

In mild cases or in cases when a large dose was already given, the therapeutic effect can be maintained by follow-up intravenous or intramuscular injection of 30 mg cerebroprotein hydrolysate reconstituted with 5 ml of sterile Water for Injection, once a day for 10 to 20 days, and then two to three times every week. The clinical long-term effect will be maintained by repeating the required dosage over several treatment periods.

### Contraindications

- Hypersensitivity to any of the product constituents.
- Status epilepticus.
- Major epilepsy: usage of this product may increase attack frequency.
- Severe renal dysfunction.
Warnings And Precautions

General

Special care is indicated in following cases:
- Allergic diathesis.
- Epileptic conditions and grand mal convulsions; cerebroprotein Hydrolysate treatment may result in an increase in the frequency of seizures
- Although there are no Indications that cerebroprotein hydrolysate causes renal stress, the product should not be administered in the presence of existing severe renal insufficiency
- Patients who take cerebroprotein hydrolysate treatment should not drive vehicles or operate machines to avoid any possible risk, though no medical evidence shows that cerebroprotein hydrolysate can reduce one's reactions to these activities.

Drug Interactions

Based on cerebroprotein hydrolysate's pharmacological profile, special attention should be paid to possible additive effects when used in conjunction with anti-depressants or monoamine oxidase inhibitors (MAOIs). In such cases, it is recommended that the dose of the antidepressant is lowered.

Cerebroprotein hydrolysate should not be mixed with balanced amino-acid solutions in one infusion.

Pregnancy and Lactation

Animal studies did not show any indication of reproductive toxicity. However, no data is available for humans. Therefore, during pregnancy and lactation, cerebroprotein hydrolysate should only be used after careful risk/benefit considerations.

Undesirable Effects

This product has the biocapability of activation, which may sometimes result in excitation effects such as active behavior, excitement and insomnia.
- Most common side effects include headache, nausea, vertigo, increased sweating, agitation, fever, hallucinations, confusion, and flu like syndrome.
- In rare cases, hyperventilation, hypertension, fatigue, tremor, depression, indifference, numbness and even flu-like symptoms (for example colds, cough and respiratory infection) may show.
- A major and extremely rare adverse effect reported is convulsion.
- Rare cases may have gastrointestinal reactions with deranged appetite, digestive disorders, diarrhea, constipation, vomiting and nausea.
- In case of a quick injection, moderate fever, sweating, or even vertigo may occur. A most rare but severe adverse effect is arrhythmia or palpitation.
- In few cases, local skin hypersensitivity at injection points such as focal skin redness, itching and heat sensation, was reported.
- Allergic reaction was reported in rare cases, such as itching, focal skin vascular reaction, pains in head, neck and extremities, fever, mild back pain, shortness of breath, tremor or shock-like appearances.
- Since cerebroprotein hydrolysate is used in elderly patients, the above symptoms are, for the most part, typical for this age group and frequently occur without medication.

Overdosage
Adverse effects resulting from overdose or intoxication have not been reported.

**Incompatibility**

Cerebroprotein hydrolysate should not be mixed with balanced amino acid solutions in an infusion. Cerebroprotein hydrolysate is incompatible with solutions that change the pH (5 to 8) and with lipid containing solutions.

**Storage And Handling Instructions**

Before opening:
Store below 25°C. Protect from light.
Keep out of reach of children.

Reconstituted solutions:
From a microbiological point of view, the product should be used immediately. If not used immediately, in use storage times and conditions prior to use are the responsibility of the user, unless reconstitution has taken place in controlled and validated aseptic conditions.
Based on the result, final infusion that has been diluted with normal saline for injection under aseptic conditions can be stored up to 4 hours at room temperature of 25°C.

**Packaging Information**

CEREBROCIP Injection........A vial of 60 mg
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