

PREGNANCY AND LACTATION

Safety has not been established in pregnancy and lactation.

OVERDOSAGE

Sufficient information is not available.

PHARMACOLOGY

Pharmacodynamics

Cerebroprotein Hydrolysate is an unique neurotrophic peptidergic mixture produced by standardized enzymatic breakdown of lipid-free porcine brain proteins. It acts like endogenous neurotrophic factors as it consists of short biological peptides. Neurotrophic activity can be detected within 1 day after a single injection.

Cerebroprotein Hydrolysate enhances neurogenesis, neuronal survival, provides neuromodulatory action, increases/modulates neuronal plasticity and neuronal repair and has neuroimmunotropic actions and thus has a unique neurotrophic activity. Cerebroprotein Hydrolysate helps in Neuronal differentiation and protection against ischaemic and neurotoxic lesions. It regulates and improves neuronal metabolism. It reduces excitotoxic damage, blocks over-activation of calcium dependent proteases, and scavenges free oxygen radicals. It has been found in animal studies that early intervention with Cerebroprotein Hydrolysate reduces blood-brain and blood-cerebrospinal fluid barrier permeability changes, attenuates brain pathology and brain edema, and mitigates functional deficits caused by traumatic brain injury. It improved brain bioelectrical activity, i.e. reduced EEG ratio by increasing fast frequencies and reducing slow activities and also improves cognitive performance in tasks, evaluating attention and memory functions in post acute traumatic brain injury patients.

Neuronal survival enhancement is produced through effect on Calpain. Calpain hyper-activation is implicated in a number of neurodegenerative disorders. Cerebroprotein Hydrolysate inhibits Calpain. Neuro-immunotropic activity is produced by inhibition of microglial activation and expression of IL- 1 beta. This reduces inflammation. Neuromodulatory effect is produced by increasing GLUT- 1 expression. GLUT-1 is responsible for more than 90% of glucose transport to brain. Neuronal plasticity is produced by reduction of amyloid beta accumulation, increased MAP 2 and synaptophysin synthesis.

Pharmacokinetics

Neurotrophic activity can be detected within 1 day after a single injection. Sufficient information on Pharmacokinetics is not available.

Storage : Store in a cool, dry & dark place, below 25°C. Protect from direct light & moisture.

Keep out of reach of children.

Shelf Life 24 Months

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.

Marketed by:

windlas

Windlas Biotech Limited
(A WHO GMP Certified Company)

40/1, Mohabewala Industrial Area,

Dehradun-248110, Uttarakhand

TM: Trademark under Registration

Manufactured by:

Protech Telelinks

(A WHO-GMP Certified Company)

Mauza Ogli, Suketi Raod, Kala Amb,

Dist. Sirmour, (H.P.) 173030 INDIA

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

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Cerebroprotein Hydrolysate Injection 60mg

CEREBROWIN™-60

Composition

Each vial contains:

Cerebroprotein Hydrolysate 2100 mg

Eq. to Nitrogen 60 mg

(A Sterile Lyophilized Powder)

Dosage Form

Powder for solution for infusion, Single use only

USES

Cerebroprotein Hydrolysate has been found to be useful in Traumatic brain injury, Acute ischaemic stroke, Vascular dementia, Extrapontine myelinolysis and Alzheimer's disease (AD).

DOSAGE AND ADMINISTRATION

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 given in a dose of 60 -180 mg once daily for 10-20 days. It should be slowly infused in 250 ml saline in 60-120 minutes. Maintenance doses (30 mg) can be given by I.M. route. It should not be mixed with amino acid solutions in the infusion bottle. Doses of antidepressants should be reduced if used with Cerebroprotein Hydrolysate. Cerebroprotein Hydrolysate Inj. can be given with other neuroprotective agents like Edaravone, Citicoline & Piracetam safely.

Method of administration:

IV / IM (maintenance dose)

CONTRAINDICATIONS

Contraindications include hypersensitivity, epilepsy and severe renal impairment.

WARNINGS AND PRECAUTIONS

There is lack of information on the dosage beyond 180 mg/day. Hence, caution is warranted for the dosage beyond recommendation. In suspicious cases of allergic reactions a test dose of Cerebroprotein Hydrolysate can be given & monitored for hypersensitivity reactions.

SIDE EFFECTS

Studies have revealed that most of the side effects are minor. Most common side effects include headache, nausea, vertigo, increased sweating, agitation, fever, hallucinations, confusion, and flu like syndrome.

DRUG INTERACTIONS

Sufficient information is not available however Cerebroprotein Hydrolysate Inj. can be given with other neuroprotective agents like Edaravone, Citicoline & Piracetam safely. Doses of antidepressants should be reduced if used along with Cerebroprotein.