Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

Ceregard Injection

2. Qualitative and quantitative composition

Each vial contains Cerebroprotein hydrolysate 2100 mg

3. Pharmaceutical form

Lyophilized Injection
A White colored lyophilized dried powder.

4. Clinical particulars

4.1 Therapeutic indications

CEREGARD contains Cerebroprotein Hydrolysate which belongs to the group of medicines called Neurotrophic agents. It is used to treat cranial injury (trauma to scalp, skull, and/or brain), inability to sustain concentration in dementia (group of disease or illness that affects your ability to think, memorize and reason), cerebrovascular disease that includes stroke (brain damage due to interruption of blood flow), and alzheimer's disease (progressive neurologic disorder that causes brain to shrink and brain cells to die).

4.2 Posology and method of administration

Recommended treatment is 10 to 20 days of continuous daily usage of required dosage of Cerebroprotein Hydrolysate based on patient age and illness. The usual dosage is 60-180 mg of Cerebroprotein Hydrolysate (calculated by total nitrogen). For preparing the infusion, first required dose of Cerebroprotein Hydrolysate should be dissolve 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 normal saline within 60 to 120 min. Each treatment period consist of 10 to 20 times of perfusion according to clinical need. In severe cases, especially when accompanied with insufficient cerebral vascular compensation, 60 mg to 180 mg (calculated by total nitrogen) of Cerebroprotein Hydrolysate can be prepared as infusion as detailed above in 250ml of saline and intravenously perfused. If given daily, eachtreatment cycle takes 10-20 times of continuous perfusion. Cerebroprotein Hydrolysate can be used in a combination with other required medications but any mixed injections are not allowed. In a mild cases or in a cases when a large dose was already given, the therapeutic effect can be maintained by a follow-up intravenous or intramuscular injection of 30 mg Cerebroprotein Hydrolysate reconstituted with 5ml of water for injection, started from once a day for 10 to 20 days and afterwards can be shifted to 2 to 3 times every

week. The clinical long term effect will be maintained by repeating several treatment periods.

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, the final infusion that has been diluted with normal saline for injection under aseptic conditions can be stored up to 4 hours at a room temperature of 25°C.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients of this formulation.

4.4 Special warnings and precautions for use

- 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.

4.5 Interaction with other medicinal products and other forms of interaction

- 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.

4.6 Fertility, pregnancy, and lactation

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.

4.7 Effects on ability to drive and use machines.

This medicine may cause blurred vision, dizziness, or drowsiness in some patients. It is advised that you do not perform any activities such

as driving a vehicle or operating machinery if you experience any of these symptoms during treatment with this medicine.

4.8 Undesirable effects

The most common side effects are (may affect up to 1 in 10 people)

COMMON

- Headache
- Nausea
- Vertigo (sensation of spinning)
- Increased sweating
- Agitation
- Fever
- Hallucinations
- Confusion
- Flu like symptoms such as chills, fever, sore throat, and coughing
- Anxiety

RARE

- Hyperventilation (deeper and faster breathing)
- High blood pressure
- Fatigue (weakness)
- Tremor
- Depression
- Indifference
- Numbness
- Deranged appetite
- Digestive disorders
- Diarrhoea
- Constipation
- Vomiting
- Signs of allergic reactions such as itching, focal skin vascular reaction, pain in head, neck and extremities, fever, mild back pain, shortness of breath, tremor, or shock-like appearances
- Arrhythmia or palpitation

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

No untoward effects would be expected if the entire contents of a 10 gram tube of Apovir Cream containing 500 mg of aciclovir were ingested orally. However the accidental, repeated overdose of oral aciclovir, over several days has resulted in gastrointestinal effects (nausea and vomiting) and neurological effects (headache and confusion). Aciclovir is dialysable by haemodialysis.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Mode of action

Cerebroprotein hydrolysate helps in restoring brain functions, where cerebroprotein hydrolysate works by protecting the nerve cells from toxins and lack of oxygen thus improving its survival rate. It also helps in the formation of new nerve cells by increasing nutrition supply to the brain cells and reducing the inflammatory reaction on the brain tissues which results in preventing damage to the brain cells.

5.2 Pharmacokinetic properties

The animal brain derived proteolytic peptide fraction consist 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, however on the basis of Cerebroprotein Hydrolysate can be detected in blood plasma up to 24h after a single application. Furthermore, components of Cerebroprotein Hydrolysate can cross the blood brain barrier. Preclinical in vivo experiments revealed identical pharmacodynamic action on the central nervous system 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.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Mannitol
Water for injection

6.2 Incompatibilities

None known

6.3 Shelf life

24 months

6.4 Special precautions for storage:

Store below 25^{o}C.
Keep this medicine out of the sight and reach of children.

6.5 Nature and contents of container

1 vial in 1 Carton

6.6 Special precautions for disposal and other handling:

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorization holder and manufacturing site addresses

Marketing authorization holder:
Krishna Chemists Limited
Manufacturing site address:
ARMEIN PHARMACEUTICALS PRIVATE LTD.
Survey # 494, Dharmaj - Khambhat Road,
At Bamanva Ta. Khambhat , Gujarat-388580 INDIA.

8. Marketing authorization number
H2024/CTD10791/23869

9. Date of first registration
23/02/2024

10. Date of revision of the text:
November 2024