Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

CEREGARD (CEREBROPROTEIN HYDROLYSATE FOR INJECTION 60MG)

2. Qualitative and quantitative composition

Each vial contains:

Cerebroprotein hydrolysate 2100 mg (Approximately)

Eq. to Nitrogen 60 mg

Excipients ..... q.s.

For full list of excipients, see section 6.1.

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 is 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, each

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treatment 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 25oC.

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

- Inform your doctor if you have
    - An allergic reaction to cerebroprotein hydrolysate or any ingredients in it.
    - Allergic diathesis (condition causing predisposition to develop group of allergies such as
- hay fever, allergic rhinitis, bronchial asthma, or atopic dermatitis)
    - Convulsion (repeated and uncontrolled contraction and relaxation of muscles)
    - Ever had any seizures (epilepsy or fits)
- This medicine is not recommended for use if you have:
    - Status epilepticus (condition in which seizure that lasts for more than five minutes or
- there occurs more than one seizure in five minutes)
    - Major epilepsia (seizure that causes loss of consciousness and violent muscle
- contractions)
- Should not administer cerebroprotein hydrolysate in the presence of existing severe renal
- insufficiency. And should not mix cerebroprotein hydrolysate with balanced amino-acid
- solutions in one infusion.
- This medicine is not recommended for use in patients with severe kidney dysfunction. It
- should be used with caution in patients with other kidney problems.
- Registration for KENYA CEREGARD (CEREBROPROTEIN HYDROLYSATE FOR INJECTION 60MG)
- This medicine should be used with caution in patients with liver disease.
- It may affect your ability to concentrate and drive. Hence, it is recommended not to drive or
- operate machinery until you are mentally alert.

4.5 Interaction with other medicinal products and other forms of interaction

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other

medicines.

CEREGARD could interact with anti-depressants, monoamine oxidase inhibitors (MAOIs), and

balanced amino-acid solutions.

4.6 Fertility, pregnancy and lactation

This medicine should be used cautiously in pregnant & breastfeeding women only if it is considered

clearly necessary.

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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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)

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- 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

Consult your doctor if you experience any of the following side effects:

- Arrhythmia or palpitation (faster heart rate)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It

allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare

professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA

Yellow Card in the Google Play or Apple App Store.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse reactions via the pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS): https://pv.pharmacyboardkenya.org

4.9 Overdose

Ceregard injection will be given to you only by a doctor or nurse in a hospital setting, and so it is

unlikely to receive an overdose. However, if you experience any unusual symptoms, consult your

doctor immediately.

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.

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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

As per dossier

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 25oC.

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

Manufactured By:

ARMEIN PHARMACEUTICALS PVT. LTD

MAH:

Krishna Chemists Ltd

3rd Floor Metrix Hardware, Lusaka Road, Industrial Area.

8. Marketing authorization number

H2024/CTD10791/23869

9. Date of first authorisation/renewal of the authorisation

2024 July 31

10. **Date of revision of the text**

2024 July 31