L-92, H-190 MM
Front Size

For the use of a Medical Practitioner, Hospital or a Laboratory

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Citicoline Injection IP 500mg/2ml

CEETI 500

For I.M. / I.V. Use

Composition :
Each 2 ml contains :

Citicoline Sodium IP		
Eq. to Citicoline		250 mg
Methylparaben (As preservative)	IP	0.18% w/v
Propylparaben (As preservative)	IP	0.02% w/v
Water for Injections	IP	q.s.

Therapeutic Indication
a. Cerebrovascular diseases - e.g. from ischaemia due to stroke, where Citicoline accelerates the recovery of consciousness and overcoming motor deficit. The clinical testing of Citicoline has challenged the historical concept that one can do nothing for a stroke patient after a certain period of time has transpired after the onset of the symptoms. The practicality of a drug that can be administered up to 24 hours after stroke is a key factor in evaluating the potential of Citicoline.

The results of a recent phase 3 clinical trials among patients suffering from ischaemia stroke demonstrated a statistically and clinically significant improvement in the neurological function of patients treated with optimal dose of Citicoline, 500mg daily. The potential of Citicoline as stroke therapy is underscored by the other key attributes: its oral dosage for, a 24-hour window of therapeutic opportunity following stroke, and an apparent absence of significant side effects. Preliminary evidence suggests that in a small sub-group of patients, Citicoline may reduce the size of the impact caused by stroke.

Treatment of Citicoline within the first 24 hours after onset in patients with moderate to severe stroke increases the probability of complete recovery in 3 months.
b. Head Trauma of varying severity: In a clinical trial, Citicoline accelerated the recovery from post-traumatic coma and the recuperation of walking ability, achieved a better final functional result and reduced hospital stay.

c. Cognitive disorders of diverse aetiology - e.g. senile cognitive impairment which is secondary to degenerative diseases (e.g. Alzheimer's disease) and to chronic cerebral vascular disease. Citicoline improves scores on cognitive evaluation scales and slowed the progression of Alzheimer's disease.
d. Parkinson's disease - Citicoline has also been shown to be effective as co-therapy for Parkinson's disease. Beneficial neuroendocrine, neuroimmunodulatory, and neurophysiological effects have been described. Considerable experimental evidence of effects of Citicoline on CNS dopaminergic system has accumulated. After treatment with Citicoline, regeneration of cells in rats with substantina nigra lesions has been demonstrated. Citicoline increases striatal dopamine and tyrosine hydroxylase synthesis.

Posology and method of administration
It is prescribed intravenously in the form of a bolus intravenous injection (during 5 minutes) or slow intravenous infusion (40-60 drops per minute) at strokes and head injury in acute period by 1000 - 2000 mg daily, which depends on severity of disease during 3-7 days with the subsequent change to intramuscular administration or oral administration. The intravenous way of administration is more preferable, than intramuscular.
Intramuscularly: 1-2 injections per day. It is necessary to avoid repeated administration of the drug to the same place during intramuscular administration.
At long-term impairment of consciousness continuous application of a drug from the first stages of disease is possible.
At Parkinson's disease and syndromes the recommended dose of a drug is 500 mg per day during the period of treatment throughout 3-4 weeks with breaks between them.

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Contraindications
Must not be administered to patients with hypertonia of the parasympathetic.
Hypertonia of the parasympathetic nervous system

Special warnings and precautions for use
Large doses of Citicoline could aggravate increase in cerebral blood flow in episodes of persistent intracranial hemorrhage.
In case of persistent intracranial hemorrhage, the very slow administration (30 drops/minute) is recommended, the administration of larger doses could provoke an increase of the cerebral blood flow.

Citicoline must not be administered in conjunction with medication containing clophenoxate
Interaction with other medicinal products and other forms of interaction
Citicoline potentiates the effects of L-dopa.

Pregnancy and lactation
There is inadequate evidence of safe use of Citicoline in human pregnancy. Citicoline should be used in pregnancy and lactation only if the potential benefits justify the potential risks.

Undesirable effects
Occasionally, Citicoline may exert a stimulating action of the parasympathetic system, as well as a fleeting and discrete hypotensive effect.

CV: Hypotension, tachycardia, bradycardia
GI: Stomach pain, diarrhea

Overdose
Citicoline exhibits very low toxicity profile in humans. In a short term, placebo-controlled, cross-over study, 12 healthy adults took Citicoline at daily doses of 600 and 1000 mg or placebo for consecutive five-day periods. Transient headaches occurred in four subjects on 600-mg dose, five on the 1000-mg dose, and one in placebo. No changes or abnormalities were observed in hematology, clinical biochemistry or neurological test.
The LD50 of a single IV dose of Citicoline was 4,600 mg/kg and 4,150 mg/kg in mice and rats, respectively. In an unpublished acute toxicity study, free-base Citicoline was administered to male and female rats at a dose of 2,000 mg/kg BW for 14 days. No changes in BW, deaths, clinical symptoms or gross pathological changes were observed.

Storage Conditions: Storage: Store at a temperature not exceeding 25°C. Protect from light.

To be kept out of reach of the children.

Presentation:
5 labeled ampoules in a tray & tray is packed in printed carton along with an insert.

Manufactured by: Protech Telelinks
(A WHO-GMP Certified Co.)
Mauza Ogli, Suketi Road, Kala Amb, Dist.
Sirmour 173030 (H.P.) INDIA

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