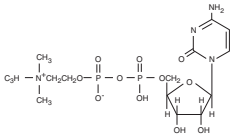
For the use of a Neurologist or a Hospital or a Laboratory only

STROLIN

(Citicoline Injection I.P. 2 ml & 4 ml)

Composition:
Each ml contains :
Citicoline Sodium I.P.
equivalent to Citicoline 250 mg
Water for injection I.P. q. s.

Introduction:
Citicoline is a pyrimidine 5-nucleotide which serves as an essential precursor in the synthesis of lecithin (phosphatidylcholine) and other phospholipids.



Its chemical name is 2-[[[5-(4-amino-2-oxo-pyrimidin-1-yl)-3,4-dihydroxy-oxolan-2-yl]methoxy-hydroxy-phosphoryl]oxy-hydroxy phosphoryl]oxyethyl-trimethyl-ammonium

Pharmacology:
The extensive damage caused by stroke requires regeneration of axons and synapses of neurons, so new membrane production is essential for the repair. Citicoline is postulated to achieve therapeutic effect in stroke due to its ability to increase the synthesis of phosphatidylcholine, the primary neuronal membrane component. It also enhances acetylcholine synthesis, and thus ameliorate symptoms caused by the stroke induced loss of cholinergic neurons.
Another mechanism by which citicoline may influence acute effect on the outcome of stroke patients relates to its ability to reduce free fatty acid accumulation at the site of injury, which prevents further damage.
Citicoline prevents or reduces the effects of ischemia and / or hypoxia in major part of animals and cellular models studies and acts in the cranial traumatic forms, reduces and limits the injuries to the membranes of the nerve cells, re-establishes the sensitivity and the function of the regulatory intracellular enzymes and accelerates the re-absorption of the cerebral oedema.
Results of experimental and clinical studies supports the use of citicoline for increasing, maintaining and repairing the membranes and the neuronal function in situations such as ischemia and traumatic injuries. In patients with senile dementia, citicoline reduces the evolution of damages.

Pharmacokinetics:
Citicoline is well absorbed after intramuscular administration. Citicoline has an absolute bioavailability of approximately 99%. Citicoline is metabolized in the liver to free choline. The liver is capable of synthesizing lecithin from choline and resynthesizing citicoline from cytidine and choline.
Due to difficulties in detecting plasma levels of citicoline itself, assays have been performed for free choline or total plasma radioactivity in terms of citicoline equivalents. Plasma choline levels are elevated significantly after oral administration. After intramuscular administration of citicoline 1000 mg, increases in plasma choline levels were seen in 0.4 hour, with levels increasing from 11 micromol/L (baseline) to 25 micromol/L. Choline derived from citicoline crosses blood brain barrier. The major portion of a dose of citicoline appears to be incorporated into tissues and / or used in biosynthetic/ biodegradation pathways, including lecithin/lipid membrane synthesis.
Small quantity of a dose is recovered in urine (2% to 3%) and in feces (less than 1%). Approximately 12% of a dose is eliminated as respiratory carbon dioxide. Elimination half life of citicoline is 3.5 hours (first peak concentration), 125 hours (second peak concentration).

Indications:
STROLIN is indicated for the treatment of disturbance of consciousness resulting from head injuries, brain operation and acute stage of cerebral infarction.

Contraindications:
Hypersensitivity to citicoline or any other component of this formulation.

Warnings and Precautions:
For patients with acute, severe and progressive disturbance of consciousness resulting from head injury or brain operation, citicoline injection should be given in conjuction with hemostatics and intracranial pressure lowering drug or such treatment as hypothermia.
For patients with disturbance of consciousness in acute stage of cerebral infarction, it is recommended to start the administration of citicoline injection within two weeks after apoplectic stroke.
Caution should be exercised when citicoline is given intramuscularly so as not to affect the tissues, nerves, etc. Intramuscular injection should be given only when justified and should be restricted to the minimum necessary. In particular, repeated injection at the same site should be avoided. Extra care should be exercised in treating prematures, newborns, nursing infants, and children. Care should be exercised to avoid injection at sites along the course of nerves. In case intense pain or backflow of blood upon insertion of the injection needle, the needle should be withdrawn immediately and injected at a different site.
In intravenous administration, inject as slowly as possible.
Since shock may occur, close monitoring of patient is mandatory. If any such signs such as drop in blood pressure, distressed feeling of the chest or dyspnea is observed, citicoline injection should be discontinued and appropriate measures, must be taken.

Pregnancy & Lactation:
There are no adequate and well controlled studies of citicoline during pregnancy and lactation. Citicoline should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised during breast-feeding because it is not known whether citicoline is excreted in human breast milk.

Drug Interactions:
Citicoline must not be used with medicines containing meclophenoxates (or centrophenoxine). Citicoline increases the effects of L-dopa.

Side Effects:
Skin rash, insomnia occurrence or intensification of numbness of paralysed / limbs (when used in patients with postapoplectic hemiplegia), nausea, abnormal laboratory values for liver function and feeling of warmth are commonly observed side effects (<1.5%).
Headache, dizziness, excitation, convulsions, anorexia, transient diplopia, transient blood pressure changes, malaise, shock, distressed feeling of the chest and dyspnea may be observed in few patients (<0.1%)

Dosage and Administration:
Disturbance of consciousness resulting from head injury or brain operation: Usually, for adults, a dose of 100-500 mg of citicoline is administered once or twice a day by intravenous drip infusion, intravenous injection or intramuscular injection. The dose may be adjusted according to the patient's age and condition.
Disturbance of consciousness: In the acute stage of cerebral infarction a dose of 1000 mg of citicoline is recommended once a day, by intramuscular injection/intravenous injection, for two weeks.

Method of administration :
Strolin injection can be administered by intramuscular slow intravenous route (3 to 5 minutes) or in dropwise infusion (drip rate : 40-60 drops/minute). Strolin injection is compatible with all intravenous isotonic solutions, it can also be mixed with hypertonic glucose serum.

Expiry date:
Do not use later than expiry date.

Storage:
Store in a cool dry place, protected from the light.

Presentation:
STROLIN is available in 2 ml and 4 ml ampoules.

Marketed by :

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