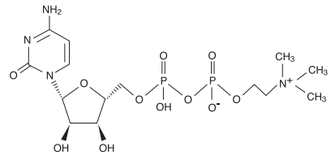
For the use of Neurologist / Specialist or a Hospital or a Laboratory only xxxxxxx-8883

STROLIN

(Citicoline Tablets 500 mg)

Composition:
Each film coated tablet contains:
Citicoline Sodium Eq. to Citicoline……500 mg
Colour: Titanium Dioxide
Description:
Structure:



Citicoline is a polarized molecule with a molecular weight of 488.33. The monosodium salt of citicoline (molecular weight: 510.31) is a white, crystalline, spongy, very hygroscopic powder that is soluble in water and almost insoluble in alcohol.
Introduction:
Citicoline is a pyrimidine 5-nucleotide which serves as an essential precursor in the synthesis of lecithin (phosphatidylcholine) and other phospholipids.
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 a 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 ameliorates 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 support 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 damage.
Pharmacokinetics:
Citicoline is well absorbed after oral 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.
Citicoline is a water-soluble compound with greater than 90-percent bioavailability. Pharmacokinetic studies on healthy adults have shown oral doses of citicoline are rapidly absorbed, with less than one percent excreted in feces. Plasma levels peak in a biphasic manner, at one hour after ingestion followed by a second larger peak at 24 hours post-dosing. Citicoline is metabolized in the gut wall and liver. The byproducts of exogenous citicoline formed by hydrolysis in the intestinal wall are choline and cytidine. Following absorption, choline and cytidine are dispersed throughout the body; enter systemic circulation for utilization in various biosynthetic pathways, and cross the blood-brain barrier for re-synthesis into citicoline in the brain.
Pharmacokinetic studies using 14C citicoline show citicoline elimination occurs mainly via respiratory CO_2 and urinary excretion, in two phases mirroring the biphasic plasma peaks. The initial peak in plasma concentration is followed by a sharp decline, which then slows over the next 4-10 hours. In the second phase, an initially rapid decline after the 24-hour plasma peak is similarly followed by a slower elimination rate. The elimination half-life is 56 hours for CO_2 and 71 hours for urinary excretion
Indications:
STROLIN is indicated for the treatment of patients with serious cerebral injuries of vascular traumatic nature with or without loss of consciousness and for the treatment degenerative damages and chronic cerebral vascular injuries in senile dementia.
Contraindications:
Hypersensitivity to citicoline or any other component of the formulation.
Warnings and Precautions:
Citicoline may cause hypotension and in case necessary the hypotensive effect can be treated with corticosteroids or sympathomimetics.
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:
Citicoline is generally well tolerated. Reported adverse events with citicoline are gastrointestinal disturbances, dizziness and asthenia.
Dosage and Administration:
The usually recommended dose of Citicoline is 500 mg to 1000 mg daily.
Elderly: No dosage adjustment is necessary in elderly.
Storage Instructions
Store at temperature not exceeding 30°C. Protect from light and moisture.
Keep out of reach of children.
Expiry Date
Do not use later than the date of expiry.
Presentation:
Strolin is available in Strip of 10's tablets

torrent PHARMA

Manufactured by :
TORRENT PHARMACEUTICALS LTD.
Baddi 173 205, Dist. Solan (H.P.) INDIA.