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

8011650-9093

STROLIN Syrup

(Citicoline Syrup) 500 mg/5 ml

Composition:

Each 5 ml contains :

Citicoline Sodium I.P. equivalent to Citicoline	500 mg
Flavoured syrupy base	q.s.
Colour : Ponceau 4R	

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. The primary mechanism by which Citicoline achieves therapeutic effect in stroke is its ability to increase the synthesis of phosphatidylcholine, the primary neuronal membrane component. Beside 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 effect of Ischemia and / or hypoxia in major parts of animals and cellular models studies and acts in the cranial traumatic forms, reduces and limits the injuries to the membranes or the nerve cells, re-establishes the sensitivity and the function of the regulatory intracellular enzymes and accelerates the re-absorption of the cerebral edema.

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 ischemic and traumatic injuries. In patients with senile dementia, Citicoline reduces the evolution of damages.

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.

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. Two peaks of plasma Citicoline equivalents have been reported after oral doses of radiolabelled Citicoline (300 mg). An initial peak is observed in approximately 1 hour (1.5 mcg / ml). Presumably related to a mixture of unchanged Citicoline and its metabolites (choline and cytidine diphosphate). A second peak of approximately 3 mcg/ml is seen 24 hours post dose, and may be due to delayed absorption of the drug or continued metabolite accumulation over this time period. Choline derived from Citicoline crosses the blood brain barrier, presumably serving as a source for acetylcholine and phosphotidylcholine (lecithin) synthesis. The major part 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:

For the treatment of disturbances of consciousness resulting from head injuries, brain operation and acute stage of cerebral infection in adults only.

Contraindications:

Hypersensitivity to citicoline or any other component of the formulation.

Warnings and Precautions:

Citicoline may cause hypotension and incase necessary the hypotensive effect can be treated. Citicoline syrup is "NOT FOR CHILDREN USE". Citicoline syrup must be prescribed by Neurologists only.

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 interaction:

Citicoline must not be used with medicine containing meclophenoxates (or centrophenoxine). Citicoline increases the effect of L-dopa.

Side effects:

Citicoline is generally well tolerated. Few adverse effects that are reported with oral Citicoline includes gastrointestinal disturbances, dizziness and fatigue.

Dosage and Administration:

The patients who are unable to swallow tablets may be given Citicoline syrup 1 to 2 teaspoon twice a day.

Expiry Date :

Do not use later than the date of expiry.

Storage:

Store in a cool place. Protect from light.

Presentation:

Strolin Syrup is available in a 60 ml bottle as ready to use syrup.

torrent

Marketed by :
TORRENT PHARMACEUTICALS LTD.
Indrad-382 721, Dist. Mehsana, INDIA.

Manufactured in India by :
LYKA LABS LIMITED
101, Shiv Shakti Industrial Estate,
Andheri Kurla Road, Andheri (East),
Mumbai-400 059.
At: Plot No. A 329/330 T.T.C Industrial Area,
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