STROLIN

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

Abbreviated Prescribing information for STROLIN (Citicoline Sodium 250 mg Injection 2 ml & 4 ml) [Please refer the complete prescribing information available at <u>www.torrentpharma.com</u>]

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

INDICATION: For the treatment of disturbance of consciousness resulting from head injuries, brain operation and acute stage of cerebral infarction.

DOSAGE AND ADMINISTRATION: Disturbance of consciousness resulting from head injury or brain operation: 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. 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.

CONTRAINDICATION: Hypersensitivity to citicoline or any other component of the formulation.

WARNINGS & 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. Extra care should be exercised in treating prematures, newborns, nursing infants, and children. In intravenous administration, inject as slowly as possible. Since shock may occur, close monitoring of patient is mandatory. If any 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.

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

ADVERSE REACTIONS: Skin rash, insomnia occurrence or intensification of numbness of paralysed / limbs (when used in patients with post apoplectic hemiplegia), nausea, abnormal laboratory values for liver function, feeling of warmth, headache, dizziness, excitation, convulsions, anorexia, transient diplopia, transient blood pressure changes, malaise, shock, distressed feeling of the chest and dyspnea.

MARKETED BY:

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IN/ STROLIN Inj/MAR 2015/01/AbPI

(Additional information is available on request)