

Abridged Prescribing Information:

Active Ingredient: STORAX PR tablet contains Citicoline 500 mg with Piracetam 800 mg

Indication: As an adjunct, STORAX PR may be beneficial in adult patients for the treatment of acute stroke.

Dosage & Administration: Adults: Dosage depends on the severity of the symptoms and the response of the individual patient. Usual recommended dosage of STORAX PR is one tablet three times in a day orally or as directed by the physician. The dosage may be increased up to 4 tablets per day. Dosage adjustment is required in those with mild to moderate renal impairment and elderly patients with diminished renal function.

Contraindication: Patients having hypersensitivity to either citicoline, piracetam, or to any other ingredient present in the formulation, Patients with severe renal insufficiency and/or hepatic impairment. **Warnings &**

Precautions: Citicoline may be associated with hypotension. In such a case, patient should be treated with corticosteroids or sympathomimetics. Piracetam should not be given to patients with hepatic impairment or severe renal impairment; dosage reduction is recommended for those with mild to moderate renal impairment. Therapy with piracetam should not be withdrawn abruptly in myoclonic patients due to the risk of inducing seizures. When used to treat cortical myoclonus, piracetam is contraindicated in patients with cerebral hemorrhage, and should be used with caution after major surgery and in those with haemostatic disorders or severe hemorrhage. **Pregnancy:** There are no adequate and well controlled studies of citicoline or piracetam in pregnant subjects. STORAX PR should be used during pregnancy only if potential benefits justify potential risks to the fetus. **Specific Population:** STORAX PR should not be given to patients with hepatic impairment.

Pediatric Patients: Use of STORAX PR is not recommended because specific safety and efficacy data of citicoline in this population are not available **Adverse Reactions:** Side effects reported with oral citicoline include gastrointestinal disturbances, dizziness, and fatigue. Rarely can it cause allergic reactions. Adverse events in piracetam recipients are generally mild and occur in a small proportion of patients. Piracetam is reported to produce insomnia or somnolence, weight gain, hyperkinesia, nervousness, and depression. Other reported adverse effects include gastrointestinal disorders such as abdominal pain, diarrhea, nausea and vomiting, hypersensitivity reactions, ataxia, vertigo, confusion, hallucinations, angioedema, and rashes.

(For details, please refer full prescribing information)

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