SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SYSCHOL - 500

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

Citicoline Sodium equivalent to Citicoline 500 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

White coloured, oblong shaped, film-coated tablets with breakline on one surface.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Acute and recovery phase of cerebral infarction (e.g., ischemia due to stroke). Cognitive dysfunction due to degenerative (i.e., Alzheimer's disease) and cerebrovascular disease. Cerebral insufficiency (e.g., dizziness, memory loss, poor concentration, disorientation) due to head trauma or brain injury.

4.2 Posology and method of administration

Recommended dose is 500 - 2000 mg per day (1-4 tablets). Doses of the preparation and treatment course duration depend on the severity of cerebral lesion and are adjusted by a doctor. Elderly patients do not need dose adjustment.

Method of administration: Oral administration.

4.3 Contraindications

Patients with hypertonia of the parasympathetic nervous system.

4.4 Special warnings and precautions for use

Large doses of Citicoline could aggravate increase in cerebral blood flow in episodes of persistent intracranial haemorrhage.

Peculiarities in usage: Citicoline preparation should be administered with caution to patients who suffer from trimethylaminuria, Parkinson's disease and patients with depression in anamnesis.

4.5 Interaction with other medicinal products and other forms of interaction

Citicoline must not be administered with products containing meclophenoxate. Citicoline enhances effects of L-dihydroxyphenylalanine and levodopa.

4.6 Fertility, pregnancy and lactation

Pregnancy and lactation: There is not enough evidence on Citicoline safety in pregnant and breastfeeding women. Citicoline should be used in pregnancy and lactation only when benefits justify the potential risks.

Use in children: No data on use in children.

4.7 Effects on ability to drive and use machines

Patients are advised not to operate heavy machinery or automobiles until the full effect of Citicoline is known. Do not consume alcohol while taking Citicoline.

4.8 Undesirable effects

Occasionally, Citicoline may exert a stimulating action of the parasympathetic system, as well as a fleeting and discrete hypotensive effect. Adverse reactions occur very rarely (<1/10000), including single cases.

System/organ class	Undesirable effects
Mentality	Hallucinations, excitement, insomnia.
Central nervous system	Headache, dizziness, tremor.
Cardiovascular system	Arterial hypertension or hypotension.
Respiratory system	Dyspnoea.
Digestive tract	Nausea, vomiting, gastric pain, hypersalivation, insignificant change of hepatic function indexes, diarrhoea.
Skin	Redness, urticaria, exanthem.
General disorders	Increase of body temperature, fever sensation, trembling and oedema.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Citicoline exhibits a very low toxicity profile in humans. In a short-term, placebo-controlled, crossover study, 12 healthy adults took Citicoline at daily doses of 600 and 1000 mg or placebo for consecutive 5-day periods. Transient headaches occurred in 4 subjects on the 600 mg dose, 5 on the 1000 mg dose and 1 in placebo. No changes or abnormalities were observed in haematology, clinical biochemistry or neurological tests.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Citicoline is a nootropic preparation. As a precursor of key ultrastructural components of the cell membrane, mainly phospholipids, Citicoline promotes restoration of damaged cell membranes, inhibits the action of phospholipase, prevents formation of free radicals and prevents cell death by acting on mechanisms of apoptosis.

It is a source of choline, increases synthesis of acetylcholine and stimulates biosynthesis of structural phospholipids in neuronal membranes. It improves the transmission of nerve impulses in cholinergic neurons, has a positive effect on plasticity of neuronal membranes and receptor function, improves cerebral blood flow, enhances cerebral metabolic processes and activates the structure of the cerebral reticular formation.

In the acute phase of stroke it reduces the volume of damaged tissue and improves cholinergic transmission. Citicoline alleviates symptoms during hypoxia and cerebral ischaemia, including memory impairment, emotional lability, lack of initiative, difficulty during daily activities and self-care. In craniocerebral injury it reduces duration of post-traumatic coma and severity of neurological symptoms. It has anti-oedema properties and reduces cerebral oedema due to its stabilising effect on the neuronal membrane. It accelerates recovery and reduces the duration and intensity of post-traumatic

syndrome. Citicoline is effective in cognitive, sensory and motor neurological disorders of degenerative and vascular aetiology.

5.2 Pharmacokinetic properties

Citicoline is well absorbed after oral, intramuscular and intravenous administration. After administration, a significant increase of choline in plasma is observed. The preparation is almost completely absorbed after oral administration. Studies have shown that the bioavailability after oral and parenteral routes of administration is similar.

The preparation is metabolised in the intestine and liver with formation of choline and cytidine. After administration it is assimilated by cerebral tissues, while choline acts on phospholipids and cytidine acts on cytidine nucleotides and nucleic acids. Citicoline quickly reaches cerebral tissues and actively integrates into cell membrane, cytoplasm and mitochondria, activating phospholipid activity.

Only a minor part of the administered dose is excreted in urine and faeces (less than 3%). Approximately 12% of the administered dose is excreted via the respiratory tract. Excretion via urine and respiratory tract has two phases: a rapid phase (urine within the first 36 hours and airways within the first 15 hours) and a slow phase. The major part of the dose is included in metabolism.

5.3 Preclinical safety data

Acute toxicity studies: For oral administration, the LD50 has been established to be 27.14 g/kg body weight for mice and 18.5 g/kg body weight for rats. A GLP study according to OECD guideline No. 423 showed no adverse effects following a single gavage dose of 2 g/kg body weight in male and female Sprague Dawley rats.

Subchronic/chronic toxicity studies: A 90-day study in rats was performed in compliance with GLP and claimed to be conducted according to OECD guideline No. 408. Groups of rats received 0, 100, 350 or 1000 mg/kg body weight per day by gavage. Clinical condition, body weight, feed and water intake, ophthalmoscopy, blood, serum and urine analyses, necropsy, organ weights and histology were evaluated.

Genotoxicity: Citicoline and its sodium salt showed no evidence of genotoxicity in bacterial reverse mutation, in vitro chromosome aberration and mammalian erythrocyte micronucleus tests. The panel concluded that there are no safety concerns related to genotoxicity.

Developmental and reproductive toxicity studies: No published studies examining possible reproductive toxicity were identified by the applicant. Unpublished data in rabbits administered 800 mg/kg body weight per day reported no signs of maternal or foetal toxicity. The applicant indicates that no adverse effects on male and female reproductive organs were reported in repeated-dose oral toxicity studies in rats and dogs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipient	Specification
Colloidal anhydrous silica (Aerosil-200)	BP
Microcrystalline Cellulose	BP
Lactose BP (Monohydrate)	BP

Maize Starch	BP
Crospovidone (Polyplasdone XL-10)	BP
Povidone (K 30)	BP
Purified water	BP
Microcrystalline Cellulose (RANQ) PH 102	BP
Talc	BP
Magnesium Stearate	BP
Hypromellose (HPMC 15 CPS)	BP
Propylene Glycol	BP
Titanium Dioxide	BP
Isopropyl Alcohol	BP
Dichloromethane (Methylene Chloride)	BP

6.2 Incompatibilities

None.

6.3 Shelf life

36 months from the date of manufacturing.

6.4 Special precautions for storage

Store below 30°C. Keep out of the reach of children.

6.5 Nature and contents of container

Primary pack: ALU/ALU strip pack of 10 tablets.

Secondary pack: Such 3 strips are packed in a printed outer carton along with a pack insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Micro Labs Limited, India
#27, Race Course Road
Bangalore - 560 001
Tel: +91 80 2237 0451-54

8. MARKETING AUTHORISATION NUMBER

H2022/CTD7236/14255

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/08/2026

10. DATE OF REVISION OF THE TEXT

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