SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Citicoline Tablets 500mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

Citicoline sodium

Equivalent to citicoline 500mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.

White, oblong shaped film-coated tablets with **ML** engraved on one surface and break line on other surface.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Acute phase of a stroke.
- Treatment of complications and consequences of a stroke.
- Craniocerebral injury and its consequences.
- Cognitive, sensitive, motor and neurological disorders caused by cerebral pathology of degenerative or vascular origin.

4.2 Posology and method of administration

Posology

Recommended dose is 500 to 2000 mg per day (1–4 tablets).

Doses of the preparation and treatment course duration depend on severity of cerebral lesion; they

are adjusted by a doctor.

Elderly patients do not need the dose adjustment.

Children: The experience of the drug administration in children is limited, so medication is prescribed only when the expected benefits outweigh any potential risk

4.3 Contraindications

- Hypersensitivity to components of the preparation.
- Patients with hypertonia of the parasympathetic nervous system.

4.4 Special warnings and precautions for use

The drug contains lactose. If you have known intolerance to some sugars, consult your doctor before taking this medicine.

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 enhances the effects of L-dihydroxyphenylalanine and levodopa.

It should not be synchronously used with drugs, which contain meclofenoxate. Alcohol should not be consumed while the preparation usage.

4.6 Fertility, pregnancy and lactation

Preparation administration during pregnancy and lactation period is possible only in case when the expected benefit for a mother over weights a potential risk for a fetus or baby.

4.7 Effects on ability to drive and use machines

In individual cases, some central nervous system adverse reactions may affect the ability to drive a motor transport or operate complicated mechanisms.

Therefore, it is necessary to be caution while driving motor transport or operating other machines during the treatment.

4.8 Undesirable effects

Side effects occur very rarely (< 1/10000), including single cases.

Psychiatric disorders: hallucinations, excitement, insomnia.

Nervous system disorders: headache, dizziness, tremor.

Cardiac disorders: arterial hypertension or hypotension.

Respiratory, thoracic and mediastinal disorders: dyspnea.

Gastrointestinal disorders: nausea, vomiting, gastric pain, hypersalivation, insignificant change of hepatic function indexes, diarrhea.

Skin and subcutaneous tissue disorders: redness, urticaria, exanthem.

General disorders and administration site conditions: increase of body temperature, fever sensation, trembling, edema.

4.9 Overdose

Intoxication appearance is unlikely due to low toxicity, even in cases when the therapeutic doses are accidentally exceeded.

In case of accidental overdose, symptomatic therapy is carried out.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Psychostimulants, agents used for ADHD and nootropics, ATC code: N06B X06.

Pharmacodynamics

Citicoline is a nootropic preparation. Citicoline as a predecessor of key ultra structural component of cell membrane (mainly phospholipids) has a wide spectrum of action: it promotes a restoration of damaged cell membranes, inhibits an action of phospholipase, preventing a formation of free radicals and prevents cell death by acting on mechanisms of apoptosis.

Citicoline is a source of choline, it increases asynthesis of acetylcholine and stimulates biosynthesis of structural (foot) phospholipids in neuron membrane.

It improves the transmission of nerve impulses in cholinergic neurons; it has a positive effect on plasticity of neuronal membranes and receptor function. It improves cerebral blood flow, enhances

cerebral metabolic processes and activates the structure of cerebral reticular formation.

In acute phase of a stroke, it reduces the volume of damaged tissue and improves cholinergic transmission.

Citicoline alleviates symptoms, which occur during hypoxia and cerebral ischemia, including memory impairment, emotional lability, lack of initiative, difficulty during daily activities and self-service.

In craniocerebral injury it reduces the duration of post-traumatic coma and the severity of neurological symptoms.

Citicoline has anti-edema properties and reduces cerebral edema due to its stabilizing effect on neuronal membrane.

It accelerates the recovery and reduces the duration and intensity of post-traumatic syndrome. Citicoline is effective in the treatment of cognitive, sensory and motor neurological disorders of degenerative and vascular etiology.

5.2 Pharmacokinetic properties

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

The preparation is metabolized in intestine and liver with the formation of choline and cytidine. After citicoline introduction it is assimilated by cerebral tissues, while cholines act on phospholipids, cytidine – on cytidine nucleoids and nucleic acids. Citicoline quickly reaches cerebral tissues and actively integrates into cell membrane, cytoplasm and mitochondria, activating an activity of phospholipids.

Only a minor part of the introduced dose is excreted with urine and feces (less than 3%). Approximately 12% of introduced dose are excreted via respiratory tract. The preparation excretion via urine and respiratory tract has two phases: first phase – rapid excretion (with urine - within the first 36 hours, via airways – within the first 15 hours), the second phase – slow excretion. A major part of the dose is included in the process of metabolism.

5.3 Preclinical safety data

Citicoline seems to be safe when taken short-term. The safety of long-term use is not known.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal anhydrous silica

Microcrystalline cellulose

Lactose

Maize Starch

Crospovidone

Povidone

Purified water

Talc

Magnesium Stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months.

6.4 Special precautions for storage

Store below 30°C. Keep away from reach of children.

6.5 Nature and contents of container

Strip pack of 10 Tablets.

6.6 Special precautions for disposal and other handling

No special requirements

7. Marketing authorization holder

MICRO LABS LIMITED

31, Race course road

Bangalore-560001

INDIA

Marketed by :

Micro Nova Pharmaceuticals Ind.Ltd.

Plot 3, Billing Way, Oregun Industrial Estate

Ikeja, Lagos Nigeria

The Name & Address of Manufacturing site:

MICRO LABS LIMITED

92, Sipcot Industrial Complex,

Hosur-635 126, India.

8. Marketing authorization number(S)

C4-1080

9. Date of first authorization/renewal of the authorization

2nd September 2020

10. Date of revision of the text

June 2025