Citomed 100 mg/ml

Pharmaceutical form: Oral solution

Composition: *active ingredient:* citicoline sodium 104.5 mg (equivalent to 100.0 mg citicoline);
excipients: sorbitol, glycerol, methylparahydroxybenzoate, propylparahydroxybenzoate, sodium citrate dehydrate, saccharine sodium, strawberry flavor (propylene glycol), potassium sorbate, 50% solution of citric acid up to pH 5.9 - 6.1, purified water to 1.0 ml.

Pharmacological group: Nootropic agent.

Pharmacodynamics:
Citicoline stimulates the biosynthesis of structural phospholipids of the neuronal membrane as it is demonstrated in the magnetic resonance spectroscopy studies. Citicoline, through its action, improves the function of the membrane mechanisms, such as the functioning of the ionic exchange pumps and receptors inserted in the latter, the modulation of which is indispensable in the neurotransmission.
Citicoline due to its membrane stabilizing activity has properties which favour brain oedema reabsorption.
Experimental studies have shown that Citicoline inhibits the activation of some phospholipases (A1, A2, C and D), reducing the formation of free radicals, avoiding the destruction of membranous systems and preserving antioxidant defence systems as glutathione.
Citicoline preserves the neuronal energetic reserve, inhibits apoptosis and stimulates acetylcholine synthesis.
It has been experimentally shown that Citicoline also exerts a prophylactic neuroprotective effect in focal brain ischemic models.
Clinical efficacy and safety
Clinical trials have shown that Citicoline significantly increases the functional evolution of patients with acute ischemic cerebrovascular accident, coinciding with a lower growth of the brain ischemic injury in neuroimaging tests.
In patients with craniocerebral traumatisms, citicoline speeds up their recuperation and reduces duration and intensity of the post-concussional syndrome.
Citicoline improves the level of attention and consciousness and acts favorably over amnesia and cognitive and neurological disorders associated to brain ischemia.

Pharmacokinetics:

Absorption

Citicoline is well absorbed after oral, intramuscular or intravenous administration. Plasma choline levels significantly increase after the aforementioned routes. Oral absorption is nearly complete and its bioavailability is approximately the same as the intravenous route.

Distribution

The administered citicoline is widely distributed in brain structures, with a quick incorporation of the choline fraction in structural phospholipids and the cytidine fraction in cytidinic nucleotides and nucleic acids. Citicoline reaches the brain and it is actively incorporated to cellular, cytoplasmatic and mitochondrial membranes, taking part of the structural phospholipids fraction.

Biotransformation

The medication is metabolized in the intestine and in the liver to choline and cytidine.

Elimination

Only a small amount of the dose appears in urine and faeces (less than 3%). Approximately 12% of the dose is eliminated via expired CO_2. In the urinary excretion of the medication, two phases can be distinguished: a first phase, around 36 hours, where the excretion speed rapidly decreases, and a second phase where excretion speed decreases much slower. The same happens with expired CO_2, the elimination speed rapidly decreases after approximately 15 hours and later it decreases much slower.

Indications:

"Cytomed" is prescribed for:

- stroke, acute phase of cerebrovascular accident, and treatment of complications and consequences of cerebrovascular accident;
- traumatic brain injury and its neurological sequelae;
- cognitive and behavioral impairment secondary to chronic vascular and degenerative cerebral disorders.

If there is no improvement or you feel worse, you should consult with doctor.

Contraindications:

- hypersensitivity to any of the components of the drug;

- pronounced vagotonia (the predominance of the tone of the parasympathetic part of the vegetative nervous system);
- rare genetic disorders associated with fructose intolerance.

Because of the absence of sufficient clinical data, is not recommended for use in children under 18 years.

Special Warnings and precautions for use:

Talk to your doctor, pharmacist or nurse before using this medicine.

Children and teenagers

The experience in children is limited; therefore, it may only be administered when the expected therapeutic benefit is higher than any possible risk.

For more information, see the "Contraindications" section.

Interactions with other medicinal products and other forms of interaction:

Tell your doctor or pharmacist if you are taking, have recently taken or may start taking any other medicines.

Citicoline potentiates the effects of the medication containing L-Dopa.

It must not be administered concomitantly with medicaments containing Meclofenoxate.

Citomed with food, drinks and alcohol:

It may be taken dissolved in half a glass of water (120 ml), with the melas or between them.

Pregnancy and lactation:

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, talk to your doctor or pharmacist before taking this medicine.

Pregnancy

There are no adequate data from the use of Citicoline in pregnant women.

Although no adverse effects were found in animal studies, during pregnancy the drug is prescribed only in cases when the expected benefits to the mother outweigh the potential risk to the fetus.

Breastfeeding

If Citomed is prescribed in lactation period, the breastfeeding must be stopped, as the allocation data of Citicoline with human milk are absent.

Fertility

No information available.

Posology and Method of Administration

Always take this medicine exactly as recommended by your doctor or pharmacist.

If in doubt, ask your doctor or pharmacist for advice.

Driving and using machines

During treatment, caution should be exercised when performing potentially hazardous activities that require special attention and quick reactions (driving a car and other vehicles, working with moving machinery, work of dispatcher and operator, etc.).

Important information about the excipients

As the medicine contains propyl parahydroxybenzoate and methyl parahydroxybenzoate, it can cause allergic reactions (possibly delayed) and, rarely, bronchospasm (sudden shortness of breath).

Posology

Adults

The recommended dose is from 500 (5 ml) to 2000 mg (20 ml) daily, depending on the severity of the symptoms to be treated.

Elderly

Does not need any specific dose adjustment for this age group.

Children

The experience in children is limited; therefore, it may only be administered when the expected therapeutic benefit is higher than any possible risk.

The dosage and the duration of treatment depend on the severity of the brain lesions and are set by the doctor individually.

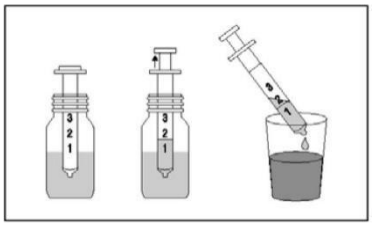
Method of administration:

Citomed solution may be taken dissolved in half a glass of water (120 ml), with the melas or between them.

Take with meals or between meals.

Patient information list for use of attached dosage syringe to bottle:

1. Place the dosage syringe into bottle (the plunger is fully lowered);
2. Carefully pull the plunger of dosage syringe, until the level of the solution is equal to the corresponding mark on the syringe.
3. Before the administration the needed quantity of solution should be dissolved with half glass of water (120 ml).



After each administration, it is recommended to wash the dosing syringe with water.

If you use more "Citomed" solution

No case of overdose has been reported.

If you forget to take the "Citomed" solution

Never take a double dose of warfarin to make up for a missed dose.

If you stop using "Citomed" solution

If you have any questions about the use of the medicine, ask your doctor, pharmacist or nurse.

Possible side effects:

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Frequency of side effects – very rare (<1/10000) (including of individual cases).

If any of the side effects indicated in the patient information list are aggravated, or any other side effects not indicated in the patient information list have been noticed, you should inform your doctor (***see table 1*** drug adverse reactions based on the classes of organ-systems (COS)).

Table 1. *Drug adverse reactions based on the classes of organ-systems (COS)*

System/organ/Class	Very rare (<1/10 000)
Mental disorders	hallucinations
Nervous System Disorders	dizziness, agitation, insomnia, tremor
Vascular disorders	arterial hypertension and hypotension
Respiratory, thoracic and mediastinal disorders	dyspnoea
Gastrointestinal disorders	nausea, vomiting, diarrhea
Immune system disorders	possible development of anaphylactic shock
Skin and subcutaneous tissue disorders	hyperemia, urticaria, exanthema, pruritus
General disorders and reactions at the injection site	fever, headache

Shelf life:

2 years.

Storage conditions:

Store below 25 ℃.

Packaging:

30 ml and 100 ml glass bottle with PE/PS dosing syringe and Patient Information Leaflet completed in a Paperboard box.

Regulatory status:

Prescription only.