**APPROVED**
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# INSTRUCTION
## for medical use

## QUANIL®

***Composition:***
*active substance:* citicoline;
1 ml of solution contains citicoline sodium equivalent to citicoline 100 mg;
*excipients:* sorbitol solution (E 420), glycerin, methyl parahydroxybenzoate sodium (E 219), propyl parahydroxybenzoate sodium (E 217), propylene glycol, sodium citrate, sodium saccharin, potassium sorbate, strawberry flavor, anhydrous citric acid, purified water.

**Pharmaceutical form.** Solution for oral use.
*Basic physico-chemical properties:* transparent colorless liquid.

**Pharmacotherapeutic group.** Other psychostimulants and nootropic agents. ATC code N06B X06.

***Pharmacological properties.***
*Pharmacodynamics.*
Citicoline stimulates the biosynthesis of structural phospholipids membranes of neurons, which has been confirmed by the data of magnetic resonance spectroscopy. Through this mechanism of action citicoline manifests functioning of such mechanisms as the work of membrane ion exchange pumps and receptors, modulation which is necessary for normal conduction of nerve impulses. Due to the stabilizing effect on the membrane of neurons citicoline reveals antiedematous properties that contribute to brain edema reabsorption.
Experimental studies have shown that citicoline inhibits the activation of certain phospholipases (A1, A2, C and D), reducing the formation of free radicals, prevents the destruction of membrane systems and retains the antioxidant protective systems such as glutathione.
Citicoline saves energy reserve of neurons, inhibits apoptosis and stimulates the synthesis of acetylcholine.
It has been experimentally proved that citicoline also exhibits prophylactic neuroprotective effect in focal cerebral ischemia.
Clinical studies have shown that citicoline significantly increases the factors of functional recovery in patients with acute ischemic stroke, which coincides with a slowdown of growth ischemic brain lesions according to the data of neuroimaging.
In patients with traumatic brain injury citicoline speeds up recovery and reduces the duration and intensity of post-traumatic syndrome.
Citicoline improves attention and consciousness, cognitive and neurological disorders associated with cerebral ischemia, reduces the manifestations of amnesia.
*Pharmacokinetics.*
Citicoline is well absorbed after oral administration. After administration of the drug, a significant increase in the level of choline in plasma is observed. When oral administration, the drug is almost completely absorbed. Studies have shown that the bioavailability of the oral and intravenous routes of administration is virtually identical.
The drug is metabolized in the intestine and in the liver with the formation of choline and cytidine.

After administration, citicoline is widely distributed in the brain structures with fast inclusion of the choline faction into structural phospholipids and cytidine fraction into cytidine nucleotides and nucleic acids. In the brain citicoline is embedded in the cell, cytoplasmic and mitochondrial membranes by participating in the construction of phospholipid fractions.
Only a very small amount of the dose is detected in the urine and feces (less than 3%). Approximately 12% of the dose is excreted through $CO_2$ by inhalation. During the excretion in the urine, two phases are distinguished: the first phase is within 36 hours, in which the elimination rate decreases rapidly, and the second phase is the one in which the elimination rate decreases much more slowly. The same phasing is observed in excretion through the respiratory tract. The elimination rate of $CO_2$ decreases rapidly for about 15 hours, then it decreases much more slowly.

**Clinical characteristics.**
***Indications.***
- Stroke, acute phase disorders of cerebral circulation and treatment of complications and the consequences of stroke.
- Craniocerebral injury and its neurological consequences.
- Cognitive impairment and behavioral disorders, resulting from chronic diseases and degenerative brain disorders.

***Contraindications.***
- Hypersensitivity to citicoline or any other drug components.
- Increased tone of the parasympathetic nervous system.

***Interaction with other medicinal products and other forms of interaction.***
Citicoline increases the effect of levodopa. Do not prescribe the drug simultaneously with drugs containing meclofenoxat.

***Administration details.***
If you have intolerance to some sugars, consult your doctor before taking this drug because the product contains sorbitol solution. Sodium propylparahydroxibenzoate (E 217), methyl parahydroxybenzoate sodium (E 219), that are contained in the drug, may cause allergic reactions (possibly delayed).

*Use during pregnancy or breast feeding.*
There are no sufficient data on the use of citicoline in pregnant women. There are no data on citicoline excretion into the breast milk and its effect on the fetus is unknown. Therefore, during pregnancy or breast feeding the drug should be used only when the expected therapeutic benefits to the mother outweigh the potential risk to the fetus.

*Effects on ability to drive a car or use machines.*
In some cases some adverse reactions of the central nervous system can affect the ability to drive motor transport or operate complex machinery.

***Dosage and administration.***
The drug Quanil is used orally, regardless of meals.
The recommended dose for adults is from 500 mg (5 ml) to 2000 mg (20 ml) per day, divided in 2-3 doses depending on the severity of the symptoms.
The drug previously mixed with small amount of water, is taken using a measuring cup. The measuring cup should be washed with water after each use. A single use plastic syringe without a needle can be used for measuring the dose.
Drug dosage and treatment duration depend on the severity of brain lesions and are determined by the doctor individually.
*Elderly patients* do not require dosage adjustment.

*Children.*

The experience of using the drug in children is limited.

***Overdose.***
Overdose cases have not been reported.

***Adverse reactions.***
*Nervous system:* severe headache, vertigo, hallucinations.
*Cardiovascular system:* arterial hypertension, arterial hypotension, tachycardia.
*Respiratory system:* dyspnea.
*Digestive system:* nausea, vomiting, diarrhea.
*Immune system:* allergic reactions including: rash, hyperemia, exanthema, urticaria, purpura, pruritus, angioedema, anaphylactic shock.
*General reactions*: chills.

***Shelf life.***
3 years.

**Storage conditions.**
Store in the original package at the temperature below 25 ºC. Do not freeze and do not cool. During storage, light opalescence is possible, which disappears when keeping the drug at indoor temperature (≈ 20 ºC). Keep out of reach of children.

**Package.**
30 ml or 100 ml are in bottles № 1. Each bottle is in a carton package together with a measuring cup.

**Condition of supply.**
By prescription.

**Manufacturer.**
“KUSUM PHARM” LLC.

**Address.**
40020, Ukraine, Sumy region, Sumy, Skryabina Str., 54.

or

**Manufacturer.**
LLC “GLADPHARM LLC”.

**Address of manufacturer and manufacturing site.**
40020, Ukraine, Sumy region, Sumy, Davydovskoho Hryhoriia Str., 54.

**Last revision date.**
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