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INSTRUCTION
for medical use

QUANIL®

Composition:
active substance: citicoline;
Each ampoule contains 522.5 mg of citicoline monosodium equivalent to 500 mg of citicoline or 1045 mg of citicoline monosodium equivalent to 1000 mg of citicoline;
excipients: sodium hydroxide or hydrochloric acid solution for pH adjustment, water for injections.

Pharmaceutical form. Solution for injections.
Basic physicochemical properties: clear colorless solution.

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

Pharmacological properties.
Pharmacodynamics.
Citicoline stimulates the biosynthesis of structural phospholipids of the neuronal membrane as it is demonstrated in the magnetic resonance spectroscopy studies. Citicoline, through this action, improves the function of the membrane mechanisms, such as the functioning of the ionic exchange pumps and receptors, the modulation of which is indispensable in the neurotransmission.
Citicoline due to its membrane stabilizing activity has properties which favor brain edema 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 defense systems as glutation.
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 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 neuro imaging tests.
In patients with craniocerebral trauma, citicoline speeds up their recuperation and reduces the duration and intensity of the post-traumatic syndrome.
Citicoline improves the level of attention and consciousness, cognitive and neurological disorders associated to brain ischemia and acts favorably over amnesia.
Pharmacokinetics.

Plasma choline levels significantly increase after the injection. The drug product is metabolized in the intestine and in the liver to choline and cytidine.
The administered of 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.
Only a small amount of the dose appears in urine and feces (less than 3%). Approximately 12% of the dose is eliminated via CO_2. In the urinary excretion of the drug, 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 when it is excreted through pathways of the respiratory system. The elimination speed of CO_2 rapidly decreases after approximately 15 hours and later it decreases much slower.

Clinical characteristics.

Indications.

Stroke, acute phase of disorder of cerebral circulation and treatment of complications and sequel of disorders of cerebral circulation.
Traumatic brain injury and its neurological sequel.
Cognitive and behavioral impairment secondary to chronic vascular and degenerative cerebral disorders.

Contraindications.

Hypersensitivity to citicoline or other drug ingredients.
Patients with high tone of a parasympathetic nervous system.

Interactions with other medicinal products and other forms of interaction.

Citicoline strengthens effect of levodopa. Concomitant administration with other meclofenoxate drugs is not recommended.

Special warnings.

In case of intravenous administration, the drug should be administered slowly (within 3–5 minutes depending on the dose administered).
If the drug is administered intravenously, the infusion rate should be 40–60 drops per minute.
In case of persistent intracranial hemorrhage, the dose should not exceed 1000 mg per day and the rate of intravenous infusion should be 30 drops per minute.

Use during pregnancy and lactation.

There are no adequate data from the use of citicoline in pregnant women. Data on the excretion of citicoline in breast milk and its effect on the fetus are unknown. During pregnancy or breastfeeding, the drug can be prescribed only when the expected therapeutic benefit to the mother outweighs the potential risk to the fetus.

Ability to effect the speed of reaction when driving a car or other machinery.

In individual cases, some side effects from the central nervous system may affect the ability to drive or operate complex machinery.

Administration details.

Recommended dose for adults is 500–2000 mg/day depending on the severity of symptoms.
For intramuscular or intravenous administration.

For intravenous use administer as an injection (for 3–5 min depending on the administered dose) or as a drip (40–60 drops per minute).
Maximum dose is 2000 mg daily.
Duration of treatment depends on the disease progression and is decided by doctor.
No dose adjustments are necessary for the elderly.
Solution for injection is meant for single use. Use the medicine immediately after opening the ampoule. Dispose any remains of the medicine after use. The medicine may be mixed in all isotonic solutions for IV use and also hypertonic glucose solution.
The treatment may be continued with an oral solution if necessary.

Children.
Limited experience in treating children.

Overdose.
No cases have been reported.

Adverse reactions.
Nervous system disorders: severe headache, vertigo, hallucinations.
Cardiac disorders: arterial hypertension, arterial hypotension, tachycardia.
Respiratory, thoracic and mediastinal disorders: dyspnoea.
Gastrointestinal disorders: nausea, vomiting, diarrhea.
Immune system disorders: allergic reactions including rash, hyperemia, exanthema, urticaria, purpura, itching, angioedema, anaphylactic shock.
General disorders and administration site conditions: chills, injection-site changes.

Shelf-life.
2 years.

Storage conditions.
Store at the temperature below 25ºC.
Keep out of reach of children.

Package.
4 ml in ampoules, 5 ampoules in a blister, 2 blisters in a carton package.

Conditions of supply.
By prescription.
Manufacturer.
SOVEREIGN PHARMA PRIVATE LIMITED.

Location of manufacturer and its address of its business activity.
Survey No. 46/1–4, Kadaiya Village, Daman-396 210, India.

Date of last revision.