SPECIALIST INFORMATION LEAFLET

SERTOZIN

TRADE NAME
Sertozin

INTERNATIONAL NON-PROPRIETARY NAME
Citicoline

CHEMICAL FORMULA
Cytidine - 5' – diphosphocholine (CDP-choline) (as sodium salt)

PHARMACEUTICAL FORM
Solution for injections.
Description: clear colourless or brownish-yellow solution.

COMPOSITION
1 ampoule of the drug contains
Active substance: citicoline (as citicoline sodium) 500 mg or 1000 mg.
Excipients: sodium hydroxide, hydrochloric acid, water for injections.

ATC CODE OF THE DRUG N06BX06

PHARMACOTHERAPEUTIC GROUP
Psychostimulants and nootropics.

PHARMACOLOGICAL PROPERTIES
PHARMACODYNAMICS
Being a predecessor of essential ultrastructural components of cellular membrane (mainly phospholipids), citicoline possesses a wide spectrum of action: contributes to recovery of damaged cellular membranes, inhibits action of phospholipases by way of impedance of excessive formation of free radicals, and prevents cell death, affecting apoptosis mechanisms. In acute stroke it decreases the volume of damaged tissue and improves cholinergic transmission. In craniocerebral injury it decreases duration of posttraumatic coma and intensity of neurologic symptoms.
In chronic cerebral hypoxia citicoline is efficient in treatment of cognitive disorders, such as memory deterioration, shiftlessness, difficulties in everyday activities and self-service.
Prolonged treatment with the drug is possible, as citicoline does not influence respiration, pulse and arterial pressure.
PHARMACOKINETICS
Absorption
Citicoline absorbs well after intravenous and intramuscular injection.
Metabolism
After intravenous and intramuscular injection citicoline is metabolized in liver with formation of choline and cytidine. Plasma concentration of choline significantly increases after administration.
Distribution
Citicoline is to a large extent distributed in the brain structures with rapid implementation of choline fractions into structural phospholipids and of the cytidine fraction into cytidine nucleotides and nucleic acids. Citicoline penetrates into the brain and is actively embedded into cellular, cytoplasmatic and mitochondrial membranes, forming fractions of structural phospholipids.
Excretion
Only 15% of the administered dose of citicoline is excreted from the body: less than 3% via kidneys and about 12% with the exhaled CO_2. Renal excretion of citicoline can be divided into 2 phases: the 1st phase (about 36 hours), during which excretion speed rapidly decreases, and the 2nd phase, in which excretion

speed decreases much more slowly. The same is observed in the exhaled CO_2: excretion speed rapidly decreases after approximately 15 hours, and then decreases much more slowly.

THERAPEUTIC INDICATIONS
- acute ischemic stroke;
- convalescence period after ischemic and hemorrhagic strokes;
- craniocerebral injury, acute and reconstitution periods;
- cognitive disorders in degenerative and vascular diseases of the brain.

DOSAGE AND ADMINISTRATION
Solution for intramuscular and intravenous injections.
The drug is administered intravenously in the form of a slow injection (for 5 minutes) or drop infusion (40-60 drops per minute). Intravenous way of administration is preferable over the intramuscular one. In case of intramuscular administration avoid repeated injection of the drug into the same place.
Acute ischemic stroke and craniocerebral injury: the recommended dose is 1000 mg every 12 hours after diagnosing; treatment duration is not less than 6 weeks. 3-7 days after the beginning of treatment the way of administration cam be switched to the intramuscular (1-2 injections daily) or the oral one (if swallowing function is not disturbed).
Convalescence period after ischemic and hemorrhagic strokes, convalescence period after craniocerebral injury, cognitive disorders in degenerative and vascular diseases of the brain: the recommended dose is 500-2000 mg daily. Dosage and duration depend on severity of symptoms of the disease.
In prolonged impairments of consciousness the drug can be administered continuously beginning from the first stages of the disease.
No dose adjustment of **Sertozin** is required for the elderly patients in case of IV or IM administration.
Solution for IV and IM injection in an ampoule is intended for a single administration. Use the solution immediately after opening of the ampoule. The drug is compatible with all types of IV isotonic solutions and dextrose solutions.

CONTRAINDICATIONS
- hypersensitivity to the components of the drug;
- expressed vagotony (domination of the tone of the parasympathetic part of the vegetative nervous system).

SIDE EFFECTS
Sertozin is usually well tolerated. Incidence of unfavourable side effects is very rare (<1/10000) (including independent cases).
CNS and peripheral nervous system disorders: insomnia, headache, dizziness, agitation, tremor, numbness in the paralysed extremities.
Digestive system disorders: nausea, loss of appetite, change in activity of hepatic enzymes.
Allergic reactions: rash, skin itching, anaphylactic shock.
Other disorders: fever. In some cases citicoline may stimulate the parasympathetic system and produce a short-term change of arterial pressure.
Contact the doctor if any of the stated above side effects exacerbate or if other side effects are observed.

SPECIAL INDICATIONS
Such drugs as mannitol and corticosteroid preparations should be prescribed in order to decrease intracranial pressure in brain injuries.
Do not exceed a single 500 mg dose of citicoline in intracranial hemorrhage; the dose can be divided in this case (100-200 mg 2-3 times daily).

INFLUENCE ON ABILITY TO DRIVE AND OPERATE OTHER MECHANISMS
During treatment patients should exercise caution while driving or performing activities requiring high speed of psychomotor reactions.

PREGNANCY AND LACTATION
Administration of the drug during pregnancy is possible only when the benefit for the mother outweighs the potential risk for the fetus.

In case of necessity to administer the drug during lactation the issue of termination of breastfeeding must be solved.

PEDIATRIC USE
Efficiency and safety of the drug in children and adolescents under 18 has not been established.

DRUG INTERACTIONS
Citicoline increases the effect of levodopa.
Avoid simultaneous prescription of the drug and medicines containing meclofenoxate.
Sertozin may be administered concurrently with hemostatic drugs, intracranial antihypertensive medicines and with common perfusion liquids.

OVERDOSE
No cases of overdose have been reported due to low toxicity of the drug even in excess of therapeutic doses.

PACKAGING
4 ml of solution for injections in ampoules of colourless glass.
5 ampoules in a contour tray.
A contour tray together with an enclosed leaflet in a carton box.

STORAGE CONDITIONS
Store at temperature not exceeding 25°C.
Keep out of reach of children!

SHELF LIFE
3 years from the date of manufacture.
Do not apply after the expiry date.

SALES TERMS
Sold under prescription.

MANUFACTURER
The holder of marketing authorization is
"DR SERTUS İLAÇ SANAYİ VE TİCARET LİMİTED ŞİRKETİ", TURKEY.
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