SUMMARY PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SOMAZINA 1000 mg solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

SOMAZINA 1000 mg solution for injection is supplied in 4 ml glass ampoules. Each ampoule contains 1000 mg of citicoline (as sodium salt)

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

SOMAZINA 1000 mg solution for injection: Clear and colourless water solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Stroke, Acute phase and its neurological sequelae.
- Traumatic Brain injury and its neurological sequelae.

4.2 Posology and method of administration

Adults:

The recommended dose is from 500 to 2,000 mg/day, depending on the severity of the symptoms to be treated.

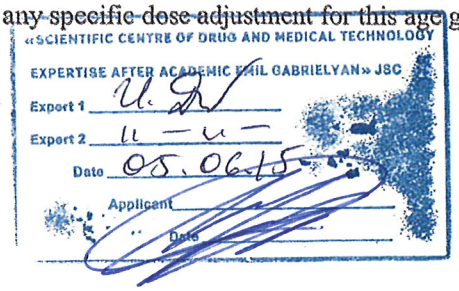
It can be administered by intramuscular, slow intravenous route (from 3 to 5 minutes depending on the administered dose) or in intravenous drop perfusion (dripping speed: 40-60 drops per minute).

See the instructions for preparation in section 6.6.

Elderly:

SOMAZINA 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 therapeutical benefit is higher than any possible risk.

4.3 Contraindications

In case of allergy to Citicoline or any excipient

It must not be administered to patients with hypertonia of the parasympathetic.

4.4 Special Warnings and precautions for use

When administered by intravenous route, the administration must be slow (from 3 to 5 minutes depending on the administered dose).

When administered by intravenous drop perfusion, the dripping speed must be 40-60 drops per minute.

In case of persistent intracranial haemorrhage, do not exceed the dose of 1000 mg daily by very slow intravenous administration (30 drops per minute).

4.5 Interaction with other medicinal products and other forms of interaction

Citicoline potentiates the effects of L-Dopa.

It must not be administered in conjunction with medicaments containing Meclofenoxate.

4.6 Pregnancy and lactation

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

SOMAZINA should not be used during pregnancy unless clearly necessary. That is, only when the expected therapeutic benefit is higher than any possible risk (see section 5.3).

4.7 Effects on the ability to drive and use machines

SOMAZINA has no influence on the ability to drive and use of machines.

4.8 Undesirable effects

Very rare (<1/10,000) (include individual notifications)
Psychiatric disorders: hallucinations
Nervous system disorders: cephalea, vertigo
Vascular disorders: arterial hypertension, arterial hypotension
Respiratory, thoracic and mediastinal disorders: dyspnoea
Gastrointestinal disorders: nausea, vomiting, occasional diarrhoea
Skin and subcutaneous tissue disorders: rash, hives, exanthemas, purple
General disorders and administration site conditions: shiver, oedema

Export 2
Date 05.06.15
Applicant
Date

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4.9 Overdose

No case of overdose has been reported

5. PHARMACOLOGOCAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other psychostimulants and nootropics.

ATC code: N06BX06

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 inserted in the latter, the modulation of which is indispensable in the neurotransmission.

Citicoline due to its membrane stabilising 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 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 neuroimagen tests.

In patients with craniocerebral traumatisms, citicoline speeds up their recuperation and reduces the duration and intensity of the post-concussional syndrome.

Citicoline improves the level of attention and consciousness and acts favourably over amnesia and cognitive and neurological disorders associated to brain ischemia.

5.2 Pharmacokinetic properties

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. The drug product is metabolized in the intestine and in the liver to choline and cytidine. 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.
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 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 with expired CO_2, the elimination speed rapidly decreases after approximately 15 hours and later it decreases much slower.

5.3 Preclinical safety data

Oral and intraperitoneal chronic toxicity studies (1.5 g/kg/day during 6 months in dogs) did not show significant abnormalities related with the administration of the drug. Intravenous administration of 300-500 mg/kg/day of citicoline during 3 months in dogs, only produced toxic signs immediately after the injection, such as occasional vomiting, diarrhoea and hyper-salivation.

800 mg/kg of Citicoline was administered to albino rabbits during the organogenesis phase, from 7th to 18th gestation day. The animals were sacrificed the 29th day and a detailed exam of foetus and their mothers was carried out. No toxicity sign were observed neither maternal nor embryo-foetal. The effects over organogenesis were inappreciable, only 10 % of the treated foetus has a slight delay in brain osteogenesis.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection and hydrochloric acid or sodium hydroxide for pH adjustment.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 30° C.

6.5 Nature and contents of the container

Carton box containing 5 glass ampoules.

6.6 Special precautions for disposal and other handling

This solution for injection is intended for single use only. It must be administered immediately after the opening of the ampoule. Unused content must be discarded. It is compatible with all intravenous isotonic solutions, it can also be mixed with hypertonic glucosed serum.

7.
MARKETING AUTHORIZATION HOLDER

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