



Citicoline

Somazine® 1000

FORMULATION:

Each mL of Somazine 1000 contains Citicoline..... 250mg
(1000mg Citicoline per 4mL ampoule)

Citicoline, a naturally occurring endogenous nucleoside, is an intermediate compound in the major pathway for the biosynthesis of the structural phospholipids of cell membranes, including neurons.

PHARMACODYNAMICS:

When administered orally, it is absorbed almost completely, and its bioavailability is approximately the same when administered intravenously.

Once absorbed, the cytidine and choline disperse widely through out the body, cross the blood-brain barrier, and reach the central nervous system (CNS), where they are incorporated into the phospholipid fraction of the cellular membrane and microsomes.

The concept that administration of exogenous Citicoline can augment the synthesis of neural membrane phospholipid is attractive, because accelerated replacement or repair plays a critical role in maintaining the healthy function of numerous physiological processes. It has shown therapeutic efficacy in a variety of diseases in which membrane disorder, dysfunction, or degeneration result in cellular and tissue ischaemia and necrosis.

PHARMACOLOGICAL PROPERTIES:

Citicoline activates the bio-synthesis of structural phospholipids in the neuronal membrane, increases cerebral metabolism and increases the level of various neurotransmitters, including acetylcholine and dopamine. Citicoline has shown neuroprotective effects in situations of hypoxia and ischaemia, as well as improved learning and memory performance in animal models of the brain aging. Furthermore, it has been demonstrated that citicoline restores the activity of mitochondrial ATPase and of membrane Na⁺/K⁺ATPase, inhibits the activation of phospholipase A2 and accelerates the re-absorption of cerebral edema in various experimental models.

INDICATIONS:

Cerebrovascular accident in acute recovery phase, symptoms and signs of cerebral insufficiency, recent cranial traumatism and their sequelae.

CONTRAINDICATIONS:

Must not be administered to patients with hypertonia of the parasympathetic.

USE IN PREGNANCY AND LACTATIONS:

There is inadequate evidence of safe use of Somazine in human pregnancy. Somazine should be used in pregnancy and lactation only if the potential benefits justify the potential risks.

PRECAUTIONS:

In case of persistent intracranial hemorrhage, the very slow administration (30 drops/minute) is recommended, the administration of larger doses could provoke an increase of the cerebral blood flow.

INCOMPATIBILITIES:

Somazine must not be administered in conjunction with medicaments containing meclofenoxate (also known as clophenoxate)

DRUG INTERACTIONS:

Somazine potentiates the effects of L-dopa

SIDE-EFFECTS:

Occasionally, citicoline may exert a stimulating action of the parasympathetic, as well as a fleeting and discrete hypotensor effect.

CAUTION:

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

DOSAGE:

Somazine 500 – 125mg/mL Injection: 1 to 2 injections daily

Somazine 1000 – 250mg/mL Injection: 1 injection daily

Dosage may be adjusted based on the seriousness of the disease. It can be administered intramuscularly, intravenously (3 to 5 minute) injection and in intravenous drop perfusion (dripping speed 40-60 drops/minute).

Somazine is compatible with all the intravenous isotonic solutions. It can also be mixed with hypertonic glucose serum. Direct administration in the vein, if it is not made very slow, can produce hypotension.

AVAILABILITY:

Somazine 1000 - 250mg/mL (1000mg/4mL ampoule): Type I Glass Ampoule x 4mL (box of 5's)

ALSO AVAILABLE:

Somazine 500 - 125mg/mL (500mg/4mL ampoule): Type I Glass Ampoule x 4mL (box of 5's)

Somazine 500mg capsule - Box x 24's

Somazine 100mg/mL adult oral drops - Bottle x 15mL

Somazine 1g tablet - 3 blistered strips x 8 tablets

STORE AT TEMPERATURES NOT EXCEEDING 25°C

Manufactured by
Ferrer Internacional, S.A.
Barcelona, Spain

Repacked by:

Natrapharm, Inc.

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Imported and Distributed by
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