Front Side

140 mm

35 mm | 35 mm | 35 mm | 35 mm | 35 mm | 35 mm

280 mm

CITICOLINE

NUROCOL™

500 mg Film-Coated Tablet
NEUROPROTECTIVE

PRODUCT NAME:
Nurocol

NAME AND STRENGTH:
Citicoline Film-Coated Tablet 500 mg

PHARMACOLOGIC CATEGORY:
Neuroprotective

PRODUCT DESCRIPTION
White oblong shaped film coated tablets with a breakline on one surface and plain on the other.

FORMULATION/COMPOSITION:
Each film-coated tablet contains:
Citicoline (as Sodium).....500 mg

PHARMACODYNAMICS/PHARMACOKINETICS:
Pharmacodynamics:
It is a Neuroprotective preparation. Citicoline as a predecessor of key ultra structural component of cell membrane (mainly phospholipids) has a wide spectrum of action: it promotes a restoration of damaged cell membranes, inhibits an action of phospholipase, preventing a formation of free radicals and prevents cell death by acting on mechanisms of apoptosis. It is a source of choline; it increases a synthesis of acetylcholine and stimulates biosynthesis of structural (foot) phospholipids in neuron membrane.
It improves the transmission of nerve impulses in cholinergic neurons; it has a positive effect on plasticity of neuronal membranes and receptor function. It improves cerebral blood flow, enhances cerebral metabolic processes and activates the structure of cerebral reticular formation.
In acute phase of a stroke it reduces the volume of damaged tissue and improves cholinergic transmission. Citicoline alleviates symptoms, which occur during hypoxia and cerebral ischemia, including memory impairment, emotional liability, lack of initiative, difficulty during daily activities and self-service. In craniocerebral injury it reduces the duration of post-traumatic coma and the severity of neurological symptoms.
Citicoline has anti-edema properties and reduces cerebral edema due to its stabilizing effect on neuronal membrane. It accelerates the recovery and reduces the duration and intensity of post-traumatic syndrome. Citicoline is effective in the treatment of cognitive, sensory and motor neurological disorders of degenerative and vascular etiology.

Pharmacokinetics:
Citicoline is well absorbed in oral, intramuscular and intravenous introduction. After the preparation introduction it is observed a significant increase of choline in plasma. The preparation is almost completely absorbed in oral administration. Studies have shown that the bioavailability in per oral and parenteral routes of introduction was similar.
The preparation is metabolized in intestine and liver with the formation of choline and cytidine. After Citicoline introduction it is assimilated by cerebral tissues, while cholines act on phospholipids, cytidine – on cytidine nucleoids and nucleic acids. Citicoline quickly reaches cerebral tissues and actively integrates into cell membrane, cytoplasm and mitochondria, activating an activity of phospholipids.
Only a minor part of introduced dose is excreted with urine and feces (less than 3%). Approximately 12% of introduced dose are excreted via respiratory tract. The preparation excretion via urine and respiratory tract has two phases: first phase – rapid excretion (with urine – within the first 36 hours, via airways – within the first 15 hours), the second phase – slow excretion. Major part of the dose is included into the process of metabolism.

INDICATIONS:
Acute and recovery phase of cerebral infarction (e.g., ischemia due to stroke). Cognitive dysfunction due to degenerative (i.e., Alzheimer's disease) and cerebrovascular disease. Cerebral insufficiency (e.g., dizziness, memory loss, poor concentration, disorientation) due to head trauma or brain injury

DOSAGE AND MODEL ROUTE OF ADMINISTRATION:
Recommended dose is 500 - 2000 mg per day (1–4 tablets).
Doses of the preparation and treatment course duration depend on severity of cerebral lesion; they are adjusted by a doctor.
Elderly patients do not need the dose adjustment.
Method of administration
Orally administer

CONTRAINDICATIONS &PRECAUTION(S), WARNING(S)
Patients with hypertonia of the parasympathetic nervous system
PRECAUTIONS & WARNINGS:
Large doses of Citicoline could aggravate increase in cerebral blood flow in episodes of persistent intracranial hemorrhage.
Peculiarities in usage:
Citicoline preparation should be administered with caution to patients who suffer from trimethylaminuria, Parkinson's disease and patients with depression in anamnesis.

PHARMACODE READING DIRECTION

280 mm

14 (L) x 8 (H) mm

PHARMACODE READING DIRECTION

673

Back Side

140 mm

35 mm | 35 mm | 35 mm | 35 mm | 35 mm | 35 mm

280 mm

PREGNANCY AND LACTATION:
Use in pregnancy & lactation:
There is not enough evidence on Citicoline safety in pregnant and breastfeeding women. Citicoline should be used in pregnancy and lactation only when benefits justify the potential risks.
Use in children: No data on use in children.

INTERACTIONS:
Citicoline must not be administered with products containing meclophenoxate
Citicoline enhances effects of L-dihydroxyphenylalanine and levodopa.

ADVERSE EFFECTS:
Occasionally, Citicoline may exert a stimulating action of the parasympathetic system, as well as a fleeting and discrete hypotensive effect.
Adverse reactions occur very rarely (< 1/10000), including single cases.
Mentality: hallucinations, excitement, insomnia.
CNS: headache, dizziness, tremor.
Cardio-vascular system: arterial hypertension or hypotension.
Respiratory system: dyspnea.
Digestive tract: nausea, vomiting, gastric pain, hyper salivation, insignificant change of hepatic function indexes, diarrhea.
Skin: redness, urticaria, exanthem.
General disorders: increase of body temperature, fever sensation, trembling, and edema.

OVERDOSAGE AND TREATMENT:
Citicoline exhibits very low toxicity profile in humans. In a short-term, placebo-controlled, crossover study, 12 healthy adults took Citicoline at daily doses of 600 and 1000 mg or placebo for consecutive 5-day periods. Transient headaches occurred in 4 subjects on 600-mg dose, 5 on the 1000-mg dose and 1 in placebo. No changes or abnormalities were observed in hematology, clinical biochemistry or neurological test.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

DOSAGE FORMS AND PACKAGING AVAILABLE:
Citicoline Tablets 500 mg are packed in Alu/Alu foil Strip of 10's (Box of 10's)

INSTRUCTIONS AND SPECIAL PRECAUTIONS FOR HANDLING AND DISPOSAL (IF APPLICABLE):
Not Applicable

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:
Marketing Authorization Holder
Brown & Burk Philippines Inc.
U-501, 5/F., SEDCCO 1 Bldg., 120 Rada cor.,
Legaspi Sts., Legaspi Village, Makati, Metro Manila

NAME AND ADDRESS OF MANUFACTURER:
MICRO LABS LIMITED
92, Sipcot, Hosur – 635 126.
Tamil Nadu, India

CAUTION STATEMENT:
FOODS, DRUGS, DEVICES, AND COSMETICS ACT PROHIBITS DISPENSING WITHOUT PRESCRIPTION.

ADR REPORTING STATEMENT:
FOR SUSPECTED ADVERSE DRUG REACTION, REPORT TO THE FDA: www.fda.gov.ph
Seek medical attention immediately at the first sign of Adverse Drug Reaction.

REGISTRATION NUMBER:
DRP-5671

DATE OF FIRST AUTHORIZATION:
19th March 2012

DATE OF REVISION OF PACKAGE INSERT:
Feb. 2017

EXG-ML01I-1038/C

Size : 140 (L) x 280 (H) mm
Drg. No.: W0990006084Z-000
Folding size: 35 x 140 mm
Carton size: 93 x 20 x 155 mm

MICRO LABS LIMITED, BANGALORE, INDIA			
1	Product Name	Nurocol	Colours Used
2	Strength	500 mg	BLACK
3	Component	Leaflet	
4	Category	Export - Philippines	
5	Dimension	140 (L) x 280 (H) mm	
6	Artwork Code	EXG-ML01I-1038/C	
7	Pharma Code	673	
8	Reason for Change	Size and New Regulation	

	Prepared by (DTP)	Checked by (PD)	Approved by			
			Head CQA	Head Production/ Packing (Site)	Head QC (Site)	Head QA (Site)
Sign	Kantharaju L.					
Date	20-07-2023					