

## **Summary of Product Characteristics for Pharmaceutical Products**

### **1. Name of the medicinal product:**

Memcolin Syrup (Citicoline Syrup 500mg/5ml)

### **2. Qualitative and quantitative composition**

Each 5mL contains:

Citicoline Sodium

Eq. to Citicoline 500 mg

For full list of excipients, see section 6.1

### **3. Pharmaceutical form**

Orange coloured viscous liquid containing flavoured syrupy base.

### **4. Clinical particulars**

#### **4.1 Therapeutic indications**

It is indicated for the treatment of patients with disturbance of consciousness resulting from a head injury or brain operation, and in the acute stage of cerebral infarction. Citicoline is taken by mouth or given as an injection to help memory loss due to aging, improve vision in people with glaucoma, and help with recovery in stroke patients. It is also used for Alzheimer disease, Parkinson disease, bipolar disorder, lazy eye, and other conditions of the brain.

#### **4.2 Posology and method of administration**

For decline in memory and thinking skills that occurs normally with age: 1000-2000 mg of citicoline per day.

For a group of eye disorders that can lead to vision loss (glaucoma): 500-1600 mg per day. For stroke: 500-2000 mg of citicoline per day starting within 24 hours of stroke.

#### **4.3 Contraindications**

Hypersensitivity to the citicoline or any other component of the formulation.

#### **4.4 Special warnings and precautions for use**

It is recommended with an intracranial pressure relieving drug and hemostatic, or a treatment such as hypothermia in patients with head injury or brain operation

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Citicoline may enhance the effects of levodopa, carbidopa and entacapone and increase dopamine level in brain. Must not be administered in conjunction with medications containing centrophenoxine.

#### **4.6 Pregnancy and Lactation**

There are no adequate and well-controlled studies of citicoline during pregnancy. Citicoline should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

#### **4.7 Effects on ability to drive and use machines**

None

#### **4.8 Undesirable effects**

Some people can have side effects such as insomnia, headache, constipation, diarrhea, nausea, stomach pain, blurred vision, chest pains, and others.

#### **4.9 Overdose**

There are no known cases of overdose in humans available for citicoline.

### **5. Pharmacological properties**

#### **5.1 Pharmacodynamic properties**

Citicoline is a complex organic molecule that functions as an intermediate in the biosynthesis of cell membrane phospholipids. Citicoline is also known as CDP-choline and cytidine diphosphatecholine (cytidine 5'-diphosphocholine). Citicoline is composed of two essential moieties, cystidine and choline, linked by a diphosphate bridge, and serves as the phosphocholine donor to 1, 2-diacylglycerol (DAG) to form phosphatidylcholine. It is a pyrimidine 5'-nucleotide, which serves as an essential precursor in the synthesis of lecithin (phosphatidylcholine) and other phospholipids. The extensive damage caused by stroke requires repair and regeneration of the axons and synapses of neurons, so new membrane production is necessary. It helps to preserve the structural and functional integrity of the neuronal membrane and counteracts the deposition of beta-amyloid, a neurotoxic protein believed to play a central role in the pathophysiology of Alzheimer's disease. It also enhances norepinephrine release and raises urinary levels of norepinephrine metabolites. Combination of citicoline and levodopa improve symptoms in patients with Parkinson's disease in small open and controlled studies.

#### **5.2 Pharmacokinetic properties**

Pharmacokinetic studies on healthy adults show oral doses of citicoline are rapidly absorbed, with less than one percent excreted in feces. Plasma levels peak in a biphasic manner, at one hour after ingestion followed by a second larger peak at 24 hours post-dosing. Citicoline is metabolized in the gut wall and liver. The byproducts of exogenous citicoline formed by hydrolysis in the intestinal wall are choline and cytidine. Following absorption, choline and cytidine are dispersed throughout the body, enter systemic circulation for utilization in various biosynthetic pathways, and cross the blood-brain barrier for re-synthesis into citicoline in the brain. Elimination mainly occurs through respiratory CO<sub>2</sub> and urinary excretion.

#### **5.3 Preclinical safety data**

Citicoline, also known as cytidine diphosphate-choline (CDP-Choline) and cytidine 5'

- diphosphocholine is a psychostimulant/nootropic. It is an intermediate in the generation of phosphatidylcholine from choline.

Studies suggest that CDP-choline supplements increase dopamine receptor densities, and suggest that CDP-choline supplementation can ameliorate memory impairment caused by environmental conditions. Preliminary research at Harvard found that citicoline supplements help improve focus and mental energy and may possibly be useful in the treatment of attention deficit disorder.

It is an ingredient in some energy drinks such as "5-Hour Energy" and is available as an over the counter nutritional supplement.

## **6. Pharmaceutical Particulars**

### **6.1 List of Excipients**

Sorbitol Solution (70%)  
Sodium Methyl Hydroxybenzoate  
Sodium Propyl Hydroxybenzoate  
Saccharin Sodium  
Citric Acid (Anhydrous)  
Orange  
Sunset Yellow FCF  
Purified Water

### **6.2 Incompatibilities**

None

### **6.3 Shelf-Life**

24 Months

### **6.4 Special Precautions for storage**

Store below 30°C, protect from light and moisture.  
Keep all medicines out of reach of children.

### **6.5 Nature and Content of container**

60ml Glass bottle packed in a carton with pack insert.

### **6.6 Special precautions for disposal and other handling**

Not applicable

## **7. Marketing Authorization Holder**

**Omnicals Pharma (Pvt.) Ltd.**

Andheri (W), Mumbai-400053, India.

## **8. Marketing Authorization Number**

H2022/CTD9749/21697

## **9. Date of first authorization/renewal of the authorization**

23/11/2025

## **10. Date of revision of the text**

23/11/2025

