SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

COLIHENZ (Citicoline Sodium Tablets)

Strength : 500 mg

Pharmaceutical form: Oral dosage form in the form of tablets

Brick red, capsule shaped, biconvex, film coated tablets plain on both sides.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each film-coated tablet contains:
Citicoline Sodium equivalent to Citicoline 500 mg

3. PHARMACEUTICAL FORM:

Oral dosage form in the form of tablets Brick red, capsule shaped, biconvex, film coated tablets plain on both sides.

4.CLINICAL PARTICULARS

4.1 Therapeutic 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
- Parkinson's disease

4.2 Posology and method of administration:

Usual Dose: 500 mg (1 tablet) once or twice daily or, as prescribed by a physician.

4.3 Contraindications:

In patients with hypertonia of the parasympathetic nervous system.
This product should not be administered to patients who have previously exhibited hypersensitivity to citicoline.

4.4 Special warnings and precautions for use:

WARNING & PRECAUTION:

Caution should be exercised in patients with history of mental illness,

during pregnancy and breast feeding.
Large doses of citicoline could aggravate increase in cerebral blood flow in episodes of persistent intracranial hemorrhage.

Use in Pregnancy:

The safety of citicoline during human pregnancy has not been established, and therefore use of this medicine is not recommended during pregnancy unless the benefits justify the potential risks and the administered dose and duration of treatment should be as low and as short as possible.

Use in Lactation:

It is not known whether citicoline or its metabolites are excreted in animal or human breast milk. Breastfeeding is therefore contraindicated during citicoline treatment.

4.5 Interaction with other medicinal products and other forms of interaction:

Citicoline must not be administered with products containing meclophenoxate.
No data regarding the pathological interferences produced by citicoline is available.

4.6 Fertility, pregnancy, and lactation: Use in Pregnancy:

The safety of citicoline during human pregnancy has not been established, and therefore use of this medicine is not recommended during pregnancy unless the benefits justify the potential risks and the administered dose and duration of treatment should be as low and as short as possible.

Use in Lactation:
It is not known whether citicoline or its metabolites are excreted in animal or human breast milk. Breastfeeding is therefore contraindicated during citicoline treatment.

4.7 Effects on ability to drive and use machines:

Not Known.

4.8 Undesirable effects:

Most people who took citicoline didn't experience problematic side effects. But some people can have side effects such as trouble in sleeping (insomnia), headache, diarrhea, low or high blood pressure, nausea, blurred vision, chest pains, and others.

Reporting of suspected adverse reactions:
Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

4.9 Overdose:

Citicoline exhibits very low toxicity profile in humans.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

The pharmacologic action of Citicoline appears to involve mechanisms that extend beyond phospholipid metabolism. Citicoline metabolites— choline, methionine, betaine, and cytidine derived nucleotides — enter a number of metabolic pathways.

Biochemical markers of cholinergic nerve transmission are known to be deficient in conditions characterized by degeneration of cholinergic neurons, such as Alzheimer's disease (AD). Citicoline modestly improves cognitive function in AD by serving as an acetylcholine precursor. The brain uses choline preferentially for acetylcholine synthesis, which can limit the amount of choline available for phosphatidylcholine production.

Citicoline has also been investigated as a therapy for stroke patients. Three mechanisms are postulated: (1) repair of the neuronal membrane via increased synthesis of phosphatidylcholine; (2) repair of damaged cholinergic neurons via potentiation of acetylcholine production; and (3) reduction of free fatty acid build-up at the site of stroke-induced nerve damage.

Citicoline protects cholinergic neurons from autocannibalism, a process in which membrane phospholipids are catabolized to provide choline for synthesis of acetylcholine. This occurs when choline supplies are depleted, necessitating
sacrifice of membrane phospholipids to maintain neurotransmission. As an exogenous source of choline for acetylcholine production, Citicoline thus spares membrane phospholipids (in particular, phosphatidylcholine) and prevents neuronal cell death accomplished.

5.2 Pharmacokinetic properties:

Citicoline is a water-soluble compound with greater than 90% bioavailability. Pharmacokinetic studies in healthy adults have shown oral doses of Citicoline to be rapidly absorbed, with less than one percent excreted in the 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.

Pharmacokinetic studies using 14C citicoline show Citicoline elimination occurs mainly via respiratory CO and urinary excretion, in two phases, mirroring the biphasic plasma peaks. The initial peak in 2 plasma concentration is followed by a sharp decline, which then slows over the next 4 —10 hours. In the second phase, an initially rapid decline after the 24-hour plasma peak is similarly followed by a slower elimination rate. The elimination half-life is 56 hours for CO and 71 hours for urinary excretion.

5.3 Preclinical Safety Data

Attached after SmPC

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Sr. No.	Name of Excipients
1.	Microcrystalline Cellulose 102
2.	Sodium Lauryl Sulphate
3.	Purified Water
4.	Isopropyl Alcohol
5.	Sodium Starch Glycolate
6.	Polacrilin Potassium
7.	Purified Talc
8.	Magnesium Stearate
9.	Hypromellose -15cps
10.	Polyethylene Glycol-6000
11.	Titanium Dioxide
12.	Red Oxide of Iron
13.	Dichloromethane

6.2 Incompatibilities:

Not applicable

6.3 Shelf life:

24 months

6.4 Special precautions for storage:

Store at a temperature not exceeding 30°C. Protect from light and moisture.

6.5 Nature and contents of the container:

10 tablets in a blister, 1 such blister is packed in a monocarton along with a

package insert. Such 10 monocartons are packed in an outer carton.

6.6 Special precautions for disposal <and other handling>:

Not applicable

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

La Renon Healthcare Pvt. Ltd.
207-208, ISCON Elegance, Circle-P, Prahlad Nagar Cross Roads, S.G. Highway, Ahmedabad-380015, Gujarat, India.

8. MARKETING AUTHORIZATION NUMBER:

H2021/CTD6173/2012ER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/September/2026

10. DATE OF REVISION OF THE TEXT:

25/02/2026