

PATIENT INFORMATION LEAFLET
CITICOLINE TABLETS 500 mg (SYSCHOL-500)



Read all of this leaflet carefully before you start taking this medicine

Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor, health care provider><or><pharmacist>.>

Prescription only medicine

In this leaflet

- a) What Syschol-500 is and what it is used for
- b) What you need to know before you take Syschol-500
- c) How to take Syschol-500
- d) Possible Side Effects
- e) How to store Syschol-500
- f) Further information

a. What Syschol-500 is and what it is used for

Syschol-500 tablet contains citicoline. They are indicated for the treatment of patients with serious cerebral injuries of vascular traumatic nature with or without loss of consciousness and for treatment of degenerative changes and chronic cerebral vascular injuries in senile dementia.

b. What you need to know before you take Syschol-500

Do not take Citicoline tablets

- If you are allergic to citicoline or any of the other ingredients of this medicine
- If you ever had serious kidney problems
- If you are hypertonic
- If you have persistent intracranial haemorrhage

If any of the above applies to you, do not take Citicoline Tablets and talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Citicoline Tablets

- if you think your kidneys may not be working perfectly. (Your doctor may need to start you on a lower dose.)

Other medicines and Citicoline Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking any of the following medicines:

- Levodopa
- Meclofenoxate
- Centrophenoxine
- Any other medicine, including medicines obtained without a prescription

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If you are taking Citicoline Tablets and you think you may be pregnant, consult your doctor immediately.

Driving and using machines

Do not to operate heavy machinery or automobiles

c. How to take Syschol-500

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

How much to medicine to take and when to take it?

Take this medicine in the dose and duration as advised by your doctor. Swallow it as a whole. Do not chew, crush or break it. Citicoline tablet may be taken with or without food, but it is better to take it at a fixed time.

Dosage adjustment is required in those with mild-to-moderate renal impairment and in the elderly population with diminished renal function.

If you take more Citicoline Tablets than you should

If you accidentally take too much, immediately go to the nearest hospital casualty department or your doctor.

If you forget to take Citicoline Tablets

Do not take a double dose to make up for a forgotten dose. Simply take the next dose as planned.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

d. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. You may notice the following side effects:

- Anxiety
- Leg edema
- Agitation
- Constipation
- Dizziness
- Fever
- Headache
- Hematuria
- Hypotension
- Urinary tract infection
- Insomnia
- Joint pain
- Depression
- Auricular Fibrillation
- ECG abnormality

e. How to store Syschol-500

Keep this medicine out of the sight and reach of children. Do not use Citicoline Tablets after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

f. further information

What Syschol-500 contains

The active substance is Citicoline

The other ingredients are: Colloidal anhydrous silica, Microcrystalline cellulose, Lactose monohydrate, Maize Starch, Crospovidone, Povidone K 30, Talc, Magnesium stearate, Hydroxy propyl methyl cellulose, Propylene Glycol, Titanium Dioxide.

What Syschol-500 looks like and contents of the pack

White coloured, oblong shaped, film-coated tablets with break line on one surface

Break line is to facilitate breaking for ease of swallowing and not for dividing into equal doses.

Strip pack of 10 tablets

Name and full physical address of Marketing Authorization Holder and Manufacturing site

Marketing Authorization Holder

MICRO LABS LIMITED

31, Race course road

Bangalore-560001

INDIA

Manufacturer

MICRO LABS LIMITED

No. 92, Sipcot Industrial Complex

Hosur -635 126 (TN)

INDIA

For any information about this medicinal product, please contact the <local representative of the> supplier

Country: Rwanda

M/s.Wessex

Pharmaceuticals (Rwanda) Ltd

C/o.Phillips Pharmaceuticals (Rwanda) Ltd

Shop No: Gf68, Kigali Modern City Market Commercial Street

Kigali, Rwanda

This leaflet was last approved in

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