

PATIENT INFORMATION LEAFLET

COGITO® 10 mg Film Coated Tablets

For oral use

Active substance: Each tablet contains 8.31 mg of memantine e equivalent to 10 mg of memantine hydrochloride.

Excipients: Bovine lactose monohydrate, microcrystalline cellulose, colloidal silicon dioxide, talc, magnesium stearate, titanium dioxide, polyvinyl alcohol, polyethylene glycol.

Before starting to use this medicine, carefully read this PACKAGE LEAFLET , because it contains important information for you.

- *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. Do not pass it on to others.*
- *It may harm them, even if their symptoms are the same as yours.*
- *Please tell your doctor that you are taking this medicine if you seek medical assistance during the use of this medicine.*
- *Follow these instructions carefully. Do not take **higher or lower** doses than recommended*

What is in this leaflet:

1. *What COGITO® is and what it is used for?*
2. *What you need to know before you use COGITO®?*
3. *How to use COGITO®?*
4. *What are possible side effects?*
5. *How to store COGITO®?*

1. What is COGITO® and what is it used for?

COGITO® is presented in blister packaging containing 30, 50, and 100 film-coated tablets. The tablets are nearly white in color, oblong-shaped, biconvex, with notches on both sides. These notches are designed to facilitate easy breaking of the tablets into equal doses.

COGITO® belongs to the group of drugs used against dementia (senility). Memory loss observed in Alzheimer's disease arises from the disruption of message signals in the brain. In the brain, there are formations called NMDA receptors which play a role in nerve stimulation important for learning and memory. COGITO® is classified within a group of drugs known as NMDA receptor antagonists, acting on the NMDA receptors to improve nerve stimulation and memory. Due to this effect, COGITO® is used in the treatment of moderate to severe stages of Alzheimer's disease.

COGITO® contains bovine lactose monohydrate.

2. What you need to know before you use COGITO®

Before using COGITO®, it is important to read the following sections and discuss any potential concerns with your doctor. You may also seek assistance from your caregiver to discuss with your doctor.

DO NOT USE COGITO® if you have the following conditions:

Do not use this medication if you are allergic (hypersensitive) to memantine hydrochloride or any of the excipients in the formula.

COGITO® should be used WITH CAUTION in following conditions:

If you have:

- a history of epileptic seizures (epilepsy),
- recently experienced a myocardial infarction (heart attack), or have heart failure or uncontrolled hypertension (high blood pressure).

Treatment should be carefully monitored, and the clinical benefit of COGITO® should be regularly reassessed by your doctor.

If you have kidney impairment, your doctor should closely monitor your kidney function and adjust the memantine dosage accordingly if necessary.

If you have renal tubular acidosis (RTA, a condition where the kidneys are unable to remove enough acid from the blood) or severe urinary tract infection, your doctor may need to adjust your medication dosage.

COGITO® should not be used concurrently with amantadine (used to treat Parkinson's disease), ketamine (used for anesthesia), dextromethorphan (commonly used in cough medications), and other NMDA antagonists.

COGITO® is not recommended for children and adolescents under 18 years old.

If any of these warnings apply to you, even if they occurred in the past, please consult your doctor.

Effects of food and drinks on COGITO®

If you have recently made significant changes to your diet or are planning to do so (such as transitioning from a regular diet to a strict vegetarian diet), it is important to inform your doctor. This is because your doctor may need to adjust your medication dosage accordingly.

Pregnancy

Before using the medication, consult your doctor or pharmacist.

If you are pregnant or planning to become pregnant, inform your doctor. The use of memantine is not recommended in pregnant women.

If you notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.

Breastfeeding

Before using the medication, consult your doctor or pharmacist.

Mothers who are using COGITO® should not breastfeed.

Ability to drive and use machinery

Your doctor will advise whether your condition allows you to drive and operate machinery safely. Additionally, COGITO® may alter your reaction capabilities, potentially making it unsafe for you to drive or operate machinery.

Important information on some of the excipients of COGITO®

COGITO® contains bovine lactose monohydrate. If your doctor has previously informed you of intolerance to certain sugars, contact your doctor before taking this medical product.

Concurrent use with other medicines

Especially the effects of the following medications may change with COGITO® and their doses may need to be adjusted by your doctor:

- amantadine (used in the treatment of Parkinson's disease and viral illnesses), ketamine (used for anesthesia purposes), dextromethorphan (used for coughs and colds)
- dantrolene, baclofen (central muscle relaxants)
- cimetidine (used in ulcer treatment), ranitidine (used in ulcer treatment), procainamide (used to regulate heart rhythm), quinidine (used to regulate heart rhythm), quinine (used in malaria treatment), nicotine (found in smoking cessation products)
- hydrochlorothiazide (or any combination containing hydrochlorothiazide) (a diuretic)
- anticholinergics (substances generally used to treat movement disorders or intestinal cramps)
- anticonvulsants (substances used to prevent and alleviate seizures)
- barbiturates (substances generally used for sleep)
- dopamine agonists (substances used in Parkinson's disease treatment such as L-dopa, bromocriptine)
- neuroleptics (substances used in the treatment of mental disorders)
- oral anticoagulants (blood thinners)

If you go to the hospital, inform your doctor that you are using COGITO®.

If you are currently using or have recently used any prescription or over-the-counter medication, please inform your doctor or pharmacist about them.

3. How to use COGITO® ?

• Instructions for appropriate use and dose/frequency of administration:

COGITO® should always be taken as recommended by your doctor. If you are unsure, ask your doctor or pharmacist.

Dosage:

The recommended dose of COGITO® for adults and elderly patients is 20 mg once daily (1 x 2 tablets). To minimize the risk of side effects, this dose should be gradually increased according to the following daily treatment schedule:

First Week	½ tablet
Second Week	1 tablet
Third Week	1 ½ tablet
Fourth Week and After	2 tablet

The treatment starts with a daily dose of 5 mg, which is half a tablet (½ tablet), and this is continued for one week. In the second week, the dose is increased to 10 mg daily (one tablet once a day), and in the third week, it is increased to 15 mg daily (one and a half tablets once a day).

From the fourth week onwards, the treatment continues with the recommended maintenance dose of 20 mg once daily (2 tablets once a day).

Treatment Duration:

Continue taking COGITO® for as long as it benefits you. Your treatment should be regularly evaluated by your doctor at scheduled intervals.

• Method and route of administration:

COGITO® should be taken orally once daily. To benefit from your medication, you should take it regularly every day at the same time. Swallow the tablets with a small amount of water. The tablets can be taken with or without food.

- **Different Age Groups:**

Use in Children: The safety and effectiveness of memantine in children and adolescents have not been established. Therefore, its use is not recommended in children under 18 years of age.

Use in Elderly: Based on clinical studies, the recommended dose for patients aged 65 and older is 20 mg per day, as described above.

- **Special precautions for use:**

Renal failure:

If you have renal failure, your doctor will decide on a dose appropriate for your condition. In this case, your kidney function should be monitored at regular intervals by your doctor.

If you have any concerns about COGITO® being too strong or too weak in its effect, talk to your doctor or pharmacist.

If you have taken more COGITO® than you should:

- Generally, using too much COGITO® should not cause harm, but you may experience increased side effects as described in the '4. Possible Side Effects' section.

- If you have taken an overdose of COGITO®, you may need medical supervision. Contact your doctor or seek medical assistance.

If you have used more COGITO® than prescribed, talk to a doctor or pharmacist.

If you forget to take COGITO®

If you forget to take your dose of COGITO®, wait until the next scheduled dose and take it at that time.

Do not double the dose to make up for the missed one.

4. Potential side effects

Like all medications, COGITO® can cause side effects in individuals sensitive to its ingredients.

Generally, observed side effects are mild to moderate in severity.

Side effects are categorized as follows:

Very common: may affect at least 1 in 10 patients.

Common: may affect less than 1 in 10, but more than 1 in 100 patients.

Uncommon: may affect less than 1 in 100, but more than 1 in 1,000 patients.

Rare: may affect less than 1 in 1,000, but more than 1 in 10,000 patients.

Very rare: may affect less than 1 in 10,000 patients.

Unknown: cannot be estimated from the available data.

If you notice any of the following, immediately inform your doctor or go to the nearest emergency department:

Uncommon:

- Heart failure
- Venous thrombosis/thromboembolism (formation of a blood clot in a vein, followed by its detachment and circulation to another part of the body)

Very rare:

- Seizures

Unknown:

- Hepatitis (inflammation of the liver)

All of these are serious side effects that may require urgent medical intervention.

If you notice any of the following, inform your doctor:

Common:

- Headache, drowsiness, constipation, increased liver function tests, dizziness, imbalance, shortness of breath, high blood pressure, and hypersensitivity

Uncommon:

- Fatigue, fungal infections, confusion, hallucinations (seeing or hearing things that are not there), vomiting, and abnormal gait

Unknown:

- Pancreatitis (inflammation of the pancreas) and psychotic reactions (perceiving things without a stimulus, involving persistent and resistant thoughts)

These are mild to moderate side effects of COGITO®.

Alzheimer's disease (memory loss due to disruptions in brain signaling), depression, suicidal thoughts, and suicide have been associated with COGITO® use. These events have been reported in patients treated with COGITO®.

If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

Reporting of side effects

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

5. Storage of COGITO®

Store COGITO® in a place where children cannot see or reach, in its original packaging.

Store below 25°C.

Use in accordance with the expiry date.

Do not use COGITO® after the expiration date printed on the packaging. The expiration date indicates the last day of the specified month.

Do not dispose of expired or unused medications in the trash! Dispose of them according to the collection system established by the Ministry of Environment, Urbanization, and Climate Change

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This leaflet has been approved <{DD month YYYY}>.

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