

PACKAGE LEAFLET: INFORMATION FOR THE USER**CENIPIL[®]**

5 & 10 mg film-coated tablets
Donepezil Hydrochloride

For the patient and/or the caregiver:

Read all of this leaflet carefully before you start taking this medicine 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 only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet or any side effect that is severe. See Section 4.

What is this leaflet:

1. What Cenipil[®] is and what it is used for
2. What you need to know before you take Cenipil[®]
3. How to take Cenipil[®]
4. Possible side effects
5. How to store Cenipil[®]
6. Other information

1. WHAT CENIPIL[®] IS AND WHAT IT IS USED FOR

Cenipil[®] (donepezil hydrochloride) belongs to a group of medicines called acetylcholinesterase inhibitors.

It is used to treat the symptoms of dementia in people diagnosed as having mild and moderately severe Alzheimer's disease. The symptoms include increasing memory loss, confusion and behavioural changes. As a result, sufferers of Alzheimer's disease find it more and more difficult to carry out their normal daily activities.

Cenipil[®] is for use in adult patients only.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CENIPIL[®]**Do not take Cenipil[®]:**

- If you are allergic (hypersensitive) to donepezil hydrochloride or to piperidine derivatives or any other ingredients of CENIPIL[®] (listed in section 6).
- If you are breast-feeding.

Warnings and precautions:

Tell your doctor or pharmacist before starting to take **Cenipil[®]** if you have or have had:

- stomach or duodenal ulcers
- seizures (fits) or convulsions
- a heart condition (irregular or very slow heart beat)
- asthma or any other long term lung disease
- liver problems or hepatitis
- difficulty of passing urine or mild kidney disease

Also tell you doctor if you are pregnant or think you might be pregnant.

Other medicines and Cenipil®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that your doctor has not prescribed for you but which you have bought yourself from a pharmacist. It may also apply to medicines you may take sometime in the future if you continue to take **Cenipil®**. This is because these medicines may weaken or strengthen the effects of **Cenipil®**.

Especially tell your doctor if you are taking any of the following types of medicines:

- other Alzheimer's disease medicines e.g. galantamine
- pain killers or treatment for arthritis e.g. aspirin, non-steroidal anti-inflammatory (NSAID) drugs such as ibuprofen or diclofenac sodium
- anticholinergic medicines e.g. tolterodine
- antibiotics e.g. erythromycin, rifampicin
- anti-fungal medicine e.g. ketoconazole
- anti-depressants e.g. fluoxetine
- anticonvulsants e.g. phenytoin, carbamazepine
- medication for a heart condition e.g. quinidine, beta-blockers (propranolol and atenolol)
- muscle relaxants e.g. diazepam, succinylcholine
- general anaesthetic
- medicines obtained without a prescription e.g. herbal remedies.

If you are going to have an operation that requires you to have a general anesthetic, you should tell your doctor and the anesthetist that you are taking **Cenipil®**. This is because your medicine may affect the amount of anesthetic needed.

Cenipil® can be used in patients with kidney disease or mild to moderate liver disease. You're your doctor first if you have kidney or liver disease. Patients with severe liver disease should not take **Cenipil®**.

Tell your doctor or pharmacist the name of your caregiver. Your caregiver will help you to take your medicine as it is prescribed.

Cenipil® with food and alcohol

Food will not influence the effect of **Cenipil®**

Cenipil® should not be taken with alcohol because alcohol may change its effect.

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.

Cenipil® should not be used while breast-feeding.

Driving and using machines

Alzheimer's disease may impair your ability to drive or operate machinery and you must not perform these activities unless your doctor tells you that it is safe to do so.

Also your medicine can cause tiredness, dizziness and muscle cramp. If you experience any of these effects, you must not drive or operate machinery.

Important information on some ingredients of Cenipil®

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **Cenipil®**.

3. HOW TO TAKE CENIPIL[®]

How much Cenipil[®] should you take?

Usually, you will start by taking 5 mg (one white tablet) every night. After one month, your doctor may tell you to take 10 mg (one yellow tablet) every night.

Swallow your **Cenipil[®]** tablet with a drink of water before you go to bed at night. The tablet strength you will take may change depending on the length of time you have been taking the medicine and on what your doctor recommends. The maximum recommended dose is 10 mg each night.

Always follow your doctor's or pharmacist's advice about how and when to take your medicine. Do not alter the dose yourself without your doctor's advice.

For how long should you take Cenipil[®]?

Your doctor or pharmacist will advise you on how long you should continue to take your tablets. You will need to see your doctor from time to time to review your treatment and assess your symptoms.

If you stop taking Cenipil[®]

Do not stop taking the tablets unless told to do so by your doctor. If you stop taking **Cenipil[®]**, the benefits of your treatment will gradually fade away.

If you take more Cenipil[®] than you should

DO NOT take more than one tablet each day. Call your doctor immediately if you take more than you should. If you cannot contact your doctor, contact the local hospital Accident and Emergency department at once. Always take the tablets and the carton with you to the hospital so that the doctor knows what has been taken.

Symptoms of overdosing include feeling and being sick, drooling, sweating, slow heart rate, low blood pressure (light-headedness or dizziness when standing), breathing problems, losing consciousness and seizures (fits) or convulsions.

If you forget to take Cenipil[®]

If you forget to take a tablet, just take one tablet the following day at the usual time. Do not take a double dose to make up for a forgotten dose. If you forget to take your medicine for more than one week, call your doctor before taking any more medicine.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported by people taking donepezil:

Tell your doctor if you have any of these effects while you are taking Cenipil[®]

Serious side effects

You must tell your doctor immediately if you notice these serious side effects mentioned. You may need urgent medical treatment.

- liver damage e.g. hepatitis. The symptoms of hepatitis are: feeling or being sick, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark colored urine (affects less than 1 user in 1000).
- stomach or duodenal ulcers. The symptoms of ulcers are: stomach pain and discomfort (indigestion) felt between the navel and breast bone (affects less than 1 user in 100).
- bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum (affects less than 1 user in 100).
- seizures (fits) or convulsions (affects less than 1 user in 100).

Very common side effects (affects more than 1 user in 10):

- diarrhoea

- feeling or being sick
- headaches

Common side effects (affects 1 to 10 users in 100):

- muscle cramp
- tiredness
- difficulty in sleeping (insomnia)
- the common cold
- loss of appetite
- hallucinations (seeing or hearing things that are not really there)
- unusual dreams including nightmares
- agitation
- aggressive behavior
- fainting
- dizziness
- stomach feeling uncomfortable
- rash
- itching
- passing urine uncontrollably
- pain
- accidents (patients may be more prone to falls and accidental injury)

Uncommon side effects (affects less than 1 user in 100):

- slow heart beat

Rare side effects (affects less than 1 user in 1000):

- stiffness, shaking or uncontrollable movement especially of the face and tongue but also of the limbs.

If a side effect gets serious or if you get any side effect that is not listed in this leaflet, talk to your doctor or pharmacist.

Reporting of side effects

If you get any side effect talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly to the National Medicines Agency (284 Mesogion Av., 15562, Cholargos, Attica Greece, Tel: + 30-21-32040-380/-337, Fax: + 30-21-06549-585, webpage: www.eof.gr). By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE CENIPIL®

DO NOT use this medicine after the expiry date which is stated on the labeling. The expiry date refers to the last day of the month.

Do not store this medicine in a temperature above 30°C. Keep out of sight and reach of children.

If your doctor tells you to stop this medicine, you should return the remaining tablets that you have not used to your pharmacist.

6. OTHER INFORMATION

What CENIPIL® contains

- The active substance of **Cenipil**[®] is donepezil hydrochloride. The 5 mg tablet contains 5mg donepezil hydrochloride and the 10 mg tablet contains 10 mg donepezil hydrochloride.
- The other ingredients are: Lactose monohydrate, Maize starch, Cellulose microcrystalline, Hydroxypropyl cellulose, Magnesium stearate. Film-coating: Talc purified, Macrogol, Hypromellose, Titanium dioxide (E171).
- Additionally, film-coating of 10mg contains Yellow iron oxide (E172).

What Cenipil[®] looks like

White film-coated tablets 5 mg

Yellow film-coated tablets of 10 mg

What is the content of the pack of Cenipil[®]

Film-coated tablets are packed in blisters in cartons of 28, 30, 56 and 60 tablets, depending on the pack size that is prescribed for you.
Not all pack sizes may be marketed.

Marketing Authorization Holder

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Legal status

This medicine is subject to medicinal prescription of a Neurologist or Psychiatrist.

This leaflet was last approved on: 07 March 2014