

CEPTIA ORODISPERSIBLE TABLET

Donepezil Hydrochloride (5mg, 10mg)

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What CEPTIA is used for

CEPTIA is a prescription medicine to treat dementia in 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.

How CEPTIA works

CEPTIA will not cure this disease, but should help your memory and improve your ability to think more clearly.

This medicine belongs to a group of medicines called acetylcholinesterase inhibitors. They are thought to work by increasing the levels of a substance (acetylcholine) in the brain involved in memory function by slowing down the breakdown of acetylcholine.

CEPTIA has not been approved as a treatment for any medical condition in children.

Before you use CEPTIA

- When you must not use it

You should not take CEPTIA

- if you are allergic to Donepezil Hydrochloride or any of the ingredients in CEPTIA or to medicines that contain piperidines.
- if you are not sure. See the end of this leaflet for a list of ingredients in CEPTIA.

Pregnancy and lactation

Do not take CEPTIA if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take CEPTIA if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Tell the doctor about all your present or past health problems. Include:

- Any heart problems including problems with irregular, slow, or fast heartbeats
- A heart condition called 'prolonged QT interval' or a history of certain abnormal heart rhythms called Torsade de Pointes or if anyone in your family has 'prolonged QT interval'
- Low levels of magnesium or potassium in your blood
- Asthma or lung problems
- Other types of memory impairment
- Any movement difficulties such as muscle stiffness or uncontrolled movements
- Seizure or convulsions
- Stomach or intestinal ulcers
- Difficulty passing urine
- Liver problems

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Be particularly sure to tell the doctor if you are taking any of the following types of medicines:

- Pain killers e.g. nonsteroidal anti-inflammatory drugs (NSAIDs).
- Medicines for heart rhythm problems e.g. amiodarone, sotalol and quinidine.
- Medicines for depression e.g. citalopram, escitalopram, amitriptyline.
- Medicines for psychosis e.g. pimozide, sertindole, ziprasidone.
- Medicines for bacterial infections e.g. clarithromycin, erythromycin, levofloxacin, moxifloxacin.

- Anti-fungal medicines e.g. ketoconazole
- Anticonvulsants e.g. phenytoin, carbamazepine
- Medication for heart condition e.g. quinidine, beta-blockers
- Muscle relaxant e.g. succinylcholine

How to use CEPTIA

- How much to use

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. Treatment is initiated at 5mg/day (once-a-day dosing). The maximum recommended dose is 10mg each night. Always follow your doctor's or pharmacist's advice about how and when to take your medicine.

- When to use it

Usually, CEPTIA is taken one tablet every night before you go to bed. The tablet should be placed on your tongue and allowed to disintegrate before swallowing, with or without water, according to your preference.

- How long to use it

Continue taking CEPTIA for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Overdose symptoms may include feeling and being sick, drooling, sweating, slow heart rate, low blood pressure, breathing

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problems, losing consciousness and seizures or convulsions.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking CEPTIA

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give CEPTIA to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Dementia may cause impairment of driving performance or compromise the ability to use machinery. Check with your doctor or pharmacist.

CEPTIA should not be taken with alcohol. Also, your medicine can cause tiredness, dizziness and muscle cramp, mainly when initiating or increasing the dose. If you experience any of these effects, you must not drive or operate machinery.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

CEPTIA may cause the following serious side effects:

- slow heartbeat and fainting. This happens more often in people with heart problems. Call the doctor right away if you faint while taking CEPTIA.
- more stomach acid. This raises the chance of ulcers and bleeding, especially when taking CEPTIA. The risk is

higher for people who had ulcers, or other NSAIDs.

- liver damage e.g. hepatitis
- seizures.
- Fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called "Neuroleptic Malignant Syndrome")
- fast, irregular heart beat and fainting, which could be symptoms of a life-threatening condition known as Torsade de Pointes (frequency cannot be estimated from the available data)

The most common side effects of CEPTIA are:

- nausea
- diarrhea
- difficulty in sleeping
- vomiting
- muscle cramps
- feeling tired
- loss of appetite
- Headache
- Hallucinations (hear, smell, taste or feel things that do not exist)
- Common cold
- Rash
- abnormal dreams and nightmares
- abdominal disturbances
- Itching
- Aggressive behaviour
- Pass urine uncontrollably
- Agitation
- dizziness

Unknown (frequency cannot be estimated)

- Fast, irregular heart beat and fainting, which could be symptoms of a life-threatening condition known as Torsade de Pointes.
- Changes in the heart activity which can be seen on an electrocardiogram (ECG) called 'prolonged QT interval'

You may report any side effects or adverse drug reactions directly to the

National Centre for Adverse Drug Reaction Monitoring by visiting the website nprra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of CEPTIA

- Storage

Store below 30 °C.

- Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

CEPTIA 5 mg: White flat round tablet debossed with "CEPTIA" on one side and "5" on the other

CEPTIA 10 mg: Yellow flat round tablet debossed with "CEPTIA" on one side and "10" on the other.

- Ingredients

- Active ingredient(s)

- Donepezil hydrochloride

- Inactive ingredients

- Mannitol (spray-dried)
- Corn starch
- Microcrystalline cellulose PH102
- Croscarmellose sodium
- Crospovidone type B
- Neotame
- Colloidal silicon dioxide
- Talc
- Magnesium stearate

Additionally, the 10mg tablet contains yellow iron oxide.

- MAL number:

CEPTIA 5 mg: MAL*****

CEPTIA 10 mg: MAL*****

Manufacturer

SRIPRASIT PHARMA CO., LTD.
216 Moo 6, Suanluang, Krathum Baen
Samut Sakhon 74110, Thailand

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Product Registration Holder

Medispec (M) Sdn Bhd
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Taman Mayang,
47301 Petaling Jaya, Selangor,
Malaysia

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