

Scheduling Status

S5

DONECEPT 5 Tablets

DONECEPT 10 Tablets

(Donepezil hydrochloride 5 mg and 10 mg)

Contains sugar: Lactulose Monohydrate 49 mg per 5 mg tablet and 98 mg per 10 mg tablet

Read all of this leaflet carefully before you start taking DONECEPT

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DONECEPT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DONECEPT is and what it is used for
2. What you need to know before you take DONECEPT
3. How to take DONECEPT
4. Possible side effects
5. How to store DONECEPT
6. Contents of the pack and other information.

1. What DONECEPT is and what it is used for

DONECEPT is indicated for the treatment of mild to moderate dementia in

patients with Alzheimer's disease.

2. What you need to know before you take DONECEPT

Do not take DONECEPT if you:

- Are hypersensitive or allergic to donepezil hydrochloride, piperidine derivatives, or to any of the inactive ingredients in DONECEPT.
- Are pregnant or breastfeeding.
- Are a child or adolescent below 18 years of age.

Warnings and precautions

Take special care with DONECEPT:

- If you are scheduled to undergo surgery, since DONECEPT may interact with certain muscle relaxants used during general anaesthesia.
- If you have been diagnosed with any heart condition (such as irregular or very slow heart beat, heart failure, a heart attack).
- If you have 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 have 'prolonged QT interval'
- If you have low levels of magnesium or potassium in your blood
- If you have previously suffered from or are currently suffering from a gastric ulcer, or if you are using non-steroidal anti-inflammatory drugs (NSAIDs), such as diclofenac or ibuprofen, since DONECEPT may increase stomach acid secretion leading to bleeding from the gut.
- If you have difficulty passing urine or mild kidney disease
- If you have seizures (fits) or convulsions
- If you suffer from asthma or chronic obstructive lung disease, such as chronic bronchitis or emphysema.

You must tell your doctor if you have any of the conditions or health problems listed above before taking DONECEPT.

It cannot be predicted how you will respond to treatment with DONECEPT. The use of DONECEPT in patients with severe Alzheimer's dementia, other types of dementia or other types of memory impairment (such as that related to aging), has not been established.

Other medicines and DONECEPT

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.

The following medicines may increase the effect of DONECEPT, you must tell your doctor if you are taking any of them while being treated with DONECEPT:

- Ketoconazole and itraconazole: used to treat fungal infections.
- Quinidine, amiodarone and sotalol: used to treat heart conditions.
- Erythromycin, clarithromycin, levofloxacin and moxifloxacin: antibiotics used to treat bacterial infections.
- Citalopram, fluoxetine, escitalopram and amitriptyline: medicines used to treat depression
- Pimozide, sertindole and ziprasidone: medicines for psychosis

The following medicines may decrease the effect of DONECEPT, you must tell your doctor if you are taking any of them while being treated with DONECEPT:

- Phenytoin, carbamazepine and phenobarbitone: used to treat or prevent seizures.
- Dexamethasone: used to treat inflammatory conditions such as arthritis.

- Rifampicin: used to treat tuberculosis (TB).

Alcohol could also decrease the effect of DONECEPT.

Tell your doctor if you are also taking any of the following medicines while being treated with DONECEPT:

- Medicines which fall under a class called anticholinergics such as atropine or ipratropium bromide.
- Medicines which fall under a class called cholinomimetics such as pilocarpine, physostigmine, succinylcholine and bethanechol.
- Medicines which fall under a class called beta blockers such as atenolol.

DONECEPT with food, drink and alcohol

Although DONECEPT can be taken with or without food, DONECEPT should be taken in the evening, just prior to going to bed.

Alcohol may decrease the effect of DONECEPT.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking DONECEPT. Do not take DONECEPT while you are pregnant or breastfeeding your baby (see “Do not take DONECEPT”).

Driving and using machines

Memory loss (Dementia) may affect your driving and ability to use machines. Furthermore, DONECEPT may make you feel dizzy and/or sleepy. You should refrain from driving a car or operating machinery should you experience dizziness or if you feel sleepy.

Ensure that you do not engage in the above activities until you are aware of the extent to which DONECEPT affects you.

DONECEPT contains lactulose monohydrate

DONECEPT contains lactulose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take DONECEPT, which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DONECEPT.

3. How to take DONECEPT

Do not share medicines prescribed for you with any other person.

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

You should take DONECEPT in the evening, just prior to retiring. The usual starting dose is 5 mg/day, which may be increased to 10 mg/day after one month, based on your doctor's assessment of you.

Your doctor will decide how long treatment with DONECEPT will last. Treatment will usually continue for as long as you derive benefit from it, provided that no side-effects or adverse events require cessation of therapy.

If you feel that DONECEPT is too strong or too weak for you, please discuss this

with your treating doctor.

If you take more DONECEPT than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

In the event of an overdosage, or if someone has taken your medicine by mistake, you, or this person, may experience side-effects such as those listed below. Symptoms resulting from overdose are those associated with cholinergic stimulation and may include nausea, vomiting, excessive production of saliva, sweating, slow heart rate, low blood pressure, breathing abnormalities, convulsions and collapse.

If you forget to take DONECEPT

Always take DONECEPT exactly as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next day, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for the forgotten individual dose. Continue with your normal dose on the regular schedule as prescribed by your doctor.

If you stop taking DONECEPT

Do not stop taking DONECEPT unless your doctor tells you to. If you have any further questions on the use of DONECEPT, ask your doctor or pharmacist.

4. Possible Side Effects

DONECEPT can have side effects

Not all side effects reported for DONECEPT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DONECEPT, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking DONECEPT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions such as a rash or itching; swelling of face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing.
- Abnormally high body temperature, muscle stiffness and altered consciousness.

These are all very serious side effects. If you have them, you may have had a serious reaction to DONECEPT. You need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Common cold or influenza symptoms,
- An eating disorder called anorexia,
- Abnormal dreams and nightmares,
- Agitation,
- Unrealistic beliefs or impressions (delusions),
- Depression,
- Hallucinations,
- Sleeplessness (insomnia),
- Headache,
- Dizziness,

- Sleepiness,
- Stomach (abdominal) disturbance,
- Frequent eye disorders,
- Eye cataracts,
- Eye irritation,
- Blurred vision,
- Diarrhoea,
- Nausea,
- Vomiting,
- Muscle cramps
- Frequent urination,
- Tiredness,
- Pain,
- Weight loss.

Less frequent side effects:

- Dehydration,
- Abnormal crying,
- Aggressive behaviour,
- Increased sexual desire (libido),
- Irritability,
- Nervousness,
- Restlessness,
- Impact on ability to communicate (aphasia),

- Impaired balance or coordination (ataxia),
- Tingling sensation in the hands and/or feet,
- Fainting,
- Seizures (fits),
- A spinning sensation (vertigo),
- Hot flushes,
- Slow heartbeat,
- High blood pressure,
- Dilation of the blood vessels,
- Low blood pressure,
- Shortness of breath,
- Sore throat,
- Bloating
- Pain or discomfort in your upper abdomen,
- Blood in the stool,
- Toothache,
- Increased salivation,
- A liver condition called hepatitis,
- Sweating,
- Itching,
- Hives,
- Discoloration of the skin,
- Muscle weakness,
- Frequent urination at night,

- Chest pain,
- Increases in creatine kinase in your blood (determined by laboratory tests),
- Accidents and bone fractures.

Frequency not known (frequency cannot be estimated from the available data):

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

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **“6.04 Adverse Drug Reaction Reporting Form”**, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8> or by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of DONECEPT.

5. How to store DONECEPT

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in a well closed container.
- Protect from light.
- ~~Store out of reach of children.~~
- Keep the blisters in the outer carton until required for use.

- Do not use after the expiry date stated on the packaging material.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

6. Contents of the pack and other information

What DONECEPT contains

The active substance is donepezil hydrochloride.

DONECEPT 5: Each tablet contains donepezil hydrochloride 5 mg.

DONECEPT 10: Each tablet contains donepezil hydrochloride 10 mg.

The other ingredients are lactulose monohydrate, microcrystalline cellulose, starch, cross carmellose sodium, colloidal anhydrous silica, magnesium stearate and opadry white 04F58804 (containing Hydroxy propyl methyl cellulose, titanium dioxide & macrogol 6000)

What DONECEPT looks like and contents of the pack

DONECEPT 5: White coloured, circular, biconvex, film-coated tablet with "5" debossed on one side and "DPZ" debossed on the other side.

DONECEPT 10: Yellow coloured, circular, biconvex, film-coated tablet with "10" debossed on one side and "DPZ" debossed on the other side.

DONECEPT 5 and 10 mg tablets are packed in transparent PVC/PE/PVDC and aluminium foil blisters of 10 tablets packed in 30's.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

Rosen Heights

Pasita Street

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RSA

Customer Care: 080 222 6662

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Registration number(s)

DONECEPT 5: 42/5.3/0490

DONECEPT 10: 42/5.3/0491

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:
The QR Code to
be generated and
included after
approval.