

## ALZEPIL® Tablets

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

### Information about ALZEPIL

ALZEPIL is available in 5 mg and 10 mg tablets for oral administration containing respectively 5 mg or 10 mg donepezil hydrochloride with the following excipients: magnesium stearate, corn starch, microcrystalline cellulose, lactose monohydrate.

Donepezil is a specific and reversible inhibitor of acetylcholinesterase in the central nervous system with little effect on acetylcholinesterase in peripheral tissues.

ALZEPIL is indicated for the treatment of dementia of the Alzheimer's type in patient with mild to moderate disease, as well as in patients with severe disease.

ALZEPIL may be used to treat other conditions as well.

### The way to take ALZEPIL

Take ALZEPIL as directed by your physician.

ALZEPIL should be taken in the evening, just prior to retiring. Donepezil can be taken with or without food.

Treatment is initiated at 5 mg once daily that should be maintained for at least one month then the dose can be increased to 10 mg once daily and then after 3 months the dosage can be titrated to 23 mg/day if necessary.

### Duration of treatment

The duration of treatment will be decided by your doctor. Do not discontinue therapy or change the dosage prescribed without consulting your doctor; you may require continuous treatment for quite some time. You should be reassessed to determine the clinical benefit of donepezil on a regular basis.

### In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted; Tertiary anticholinergics such as atropine may be used as an antidote for donepezil overdosage.

### In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

### Contraindications

This drug is contraindicated in case of known hypersensitivity to donepezil hydrochloride, piperidine derivatives or to any of the components.

### Precautions

-Inform your doctor before using this medication in case of pregnancy or lactation. This drug should be used during pregnancy only if clearly needed. This drug should not be used in nursing mothers.

-Caution should be taken when driving a car or operating dangerous machinery until you know how you respond to the drug.

-This drug must be used with caution in patients with severe cardiovascular disorders, gastrointestinal diseases including ulcer disease, hepatic impairment, and history of seizure disorders, genitourinary disorders, asthma or obstructive pulmonary disease.

-Inform your doctor that you are taking this medication before you get general anesthesia

-this drug can cause vomiting. Patients should be observed closely at initiation of treatment and after doses increase.

### Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

Donepezil hydrochloride has the potential to interfere with medications having anticholinergic activity. There is also the potential for synergistic activity with concomitant treatment

involving medications such as succinylcholine, other neuromuscular blocking agents or cholinergic agonists or beta blocking agents which have effects on cardiac conduction. Precautions should be taken with ketoconazole and quinidine which inhibit metabolism and increase effect of donepezil; while phenytoin, carbamazepine, dexamethasone, rifampin, and phenobarbital could increase the rate of elimination.

**Adverse reactions**

The most frequent adverse effects are: nausea, diarrhea, insomnia, vomiting, muscle cramps, fatigue and anorexia.

Other common adverse effects were headache, pain, accident, common cold, abdominal disturbance and dizziness. Rare cases of syncope, bradycardia, sinoatrial block and atrioventricular block were observed.

Please inform your doctor if any side effect appears or becomes bothersome.

**Storage**

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

**Pack Presentation**

ALZEPIL 5, donepezil HCl 5 mg, pack of 30 tablets

ALZEPIL 10, donepezil HCl 10 mg, pack of 30 tablets

**Issue date: 10/2010**

ALZT5/001