DOPEZIL 5 mg - DOPEZIL 10 mg

Donepezil Hydrochloride

FORMS AND PRESENTATIONS :
DOPEZIL 5 mg : round white tablet : Box of 30 tablets, PVC/Alu blister.
DOPEZIL 10 mg : round yellow tablet : Box of 30 tablets, PVC/Alu blister.
COMPOSITION : (PER TABLET)

	DOPEZIL 5 MG	DOPEZIL 10 MG
PRINCIPE ACTIF :		
Donepezil Hydrochloride (as Donepezil base)	5 mg (4,56 mg)	10 mg (9,12 mg)
Excipients :	Microcrystalline cellulose, monohydrate lactose, pregelatinized starch, magnesium stearate ...q.s.f. one tablet	
	Opadry white	Opadry yellow
List of active excipients :	Monohydrate lactose	

PHARMACOLOGICAL PROPRIETIES:
DOPEZIL is a specific and a reversible inhibitor of acetyl cholinesterase (brain prevailing cholinesterase).
THERAPEUTIC INDICATIONS :
Symptomatic treatment of mild to moderate Alzheimer's disease.
CONTRAINDICATIONS:
Patients with known hypersensitivity to donepezil chlorhydrate, to piperidine derivatives or the one of the excipients of the product.
POSOLOGY AND MODE OF ADMINISTRATION:
Posology :
The dosage depends on the duration of treatment and your doctor's directives.
Adult: Treatment should be initiated at a dose of 5 mg per day (one white tablet) in single dose in the evening before bedtime.This dosage will be maintained for at least 1 month duration necessary for the evaluation of the initial clinical response to treatment and the achievement of steady state plasma concentrations. After this period of 1 month of treatment at a dose of 5 mg / day, your doctor may increase the dose of donepezil in the maximum recommended dosage of 10 mg per day in single dose (1 tablet yellow).
Do not modify the dosage or interrupt treatment without consulting your doctor. After stopping treatment, a gradual reduction beneficial effects of donepezil was noted but no rebound effect.
Renal insufficiency : In patients with renal insufficiency, the clearance of Donepezil is not modified. So, there is no need of dosage adjustment.
Hepatic insufficiency : In cases of mild to moderate hepatic impairment, due to a possible increased exposure to donepezil, increased dosage should be adjusted according to individual tolerance to the product. There are no data in patients with severe hepatic disease.
Child: the use of donepezil is not recommended in infant and child.
Mode of administration :
Oral use – A single dose per day.
WARNING AND PRECAUTIONS OF USE:
Treatment should be initiated and supervised by an experienced physician in the diagnosis and treatment of patients with Alzheimer's disease. Treatment with donepezil should be undertaken only in the presence of a family member who can ensure regular taking of the medication by the patient.
The individual response to treatment is not predictable. The cessation of therapy should be considered when the therapeutic effect disappears. The use of donepezil in patients with severe stage of Alzheimer's disease or suffering from other types of dementia or other forms of memory disorders has not been studied.
- Anesthesia: donepezil, like any cholinesterase inhibitor, may increase muscle relaxation induced by depolarizing curares such as succinylcholine.
- Cardiovascular troubles: Because of their pharmacological activity, cholinesterase inhibitors may increase cardiac cholinergic tonus with bradycardia risk. Their incidence and severity (risk of sinus pause) are particularly high in patients with disorders of the intracardiac conduction (sino atrial block, atrioventricular block).
- Gastrointestinal disorders: Patients with ulcer or with ulcer risk (such as those with a history of ulcer disease or receiving nonsteroidal anti-inflammatory drugs) should be monitored carefully. However, clinical studies conducted with donepezil showed no increase in the incidence of ulcers or gastrointestinal bleeding compared to placebo.
- Genitourinary disorders: Although not observed in studies conducted with donepezil, cholinomimetics can induce urinary retention.
- Neurological disorders: cholinomimetics are described as potentially responsible for generalized seizures. However, convulsions can also be a manifestation of the disease. Cholinomimetics may have the potential to exacerbate or to induce extrapyramidal symptoms.
- Broncho-pulmonary disorders: Because of its cholinomimetic activity, donepezil should be prescribed with caution in patients with a history of asthma or chronic obstructive pulmonary disease.
- Concomitant administration of donepezil and other acetylcholinesterase inhibitors, cholinergic system agonists or antagonists is to be avoided.
PREGNANCY AND BREASTFEEDING:
Pregnancy :
Although no experimental or clinical study has shown teratogenesis effect of donepezil, Dopézil should not be used during pregnancy unless it is clearly necessary.
Breastfeeding:
The excretion in breast milk of donepezil is not documented and there is no study in women who are breastfeeding. As a result, women who receive donepezil should not breastfeed.
Drivers and users machines:
The donepezil had a minor to moderate influence on the ability to driving and the use of machines. However, Alzheimer's disease itself can cause a disability to drive or operate machines. The donepezil can induce fatigue, dizziness and muscle cramps, especially at the treatment initiation or dosage increasing. The ability to continue driving or operating on complex machines of patients with Alzheimer's disease treated with donepezil should be regularly evaluated by the attending physician.
DRUG INTERACTIONS:
You should report any other current treatment to your doctor or pharmacist.
The donepezil and / or its metabolites dont inhibit the metabolism of theophylline, warfarin, cimetidine or digoxin in humans.
The metabolism of donepezil is not affected by concomitant administration of digoxin or cimetidine.
In vitro studies have shown that the system of cytochrome P450 (3A4 isoenzyme and to a lesser extent 2D6) is involved in the metabolism of donepezil. Accordingly, the CYP3A4 inhibitors, such as ketoconazole, itraconazole, and erythromycin, and CYP2D6 inhibitors, such as quinidine, fluoxetine, could inhibit the metabolism of donepezil. The enzyme inducers such as rifampicin, phenytoin, carbamazepine and alcohol can decrease the concentrations of donepezil. In the absence of data about the degree of these effects inducers or inhibitors, such drug combinations should be used with caution.
The donepezil can alter the activity of other anticholinergic treatment. It can also potentiate the cholinergic activity during the concomitant use of products such as succinylcholine, other neuromuscular system blockers, cholinergic agonists or beta blockers acting on cardiac conduction.
ADVERSE EFFECTS:
Adverse events most frequently observed are: rash, pruritus, headache, fatigue, muscle cramps, diarrhea, anorexia, nausea, vomiting, urinary incontinence, hallucinations, agitation, insomnia, colds, dizziness and syncope.
Other less common side effects have been reported: pain, abdominal disorders, gastric and duodenal ulcer, bradycardies, sino-atrial and atrio-ventricular block, convulsions, extrapyramidal symptoms and a slight increase in serum musclar creatinine kinase.
OVERDOSAGE :
The median lethal dose of donepezil hydrochloride after a single oral in mice and rats is estimated, respectively, to 45 and 32 mg / kg, or about 225 to 160 times the maximum recommended dose in humans (10 mg / d). Dose dependent signs on cholinergic stimulation were observed in animals, including a reduction in spontaneous motor functions, prostration,a staggering, tearing, clonic convulsions, respiratory depression, salivation, miosis, fasciculation and body temperature decrease.
The overdose of cholinesterase inhibitors may lead to cholinergic crisis characterized by severe nausea, vomiting, salivation, sweating, bradycardia, hypotension, respiratory depression, convulsions and collapse. An increasing muscle weakness is possible, which can lead to death if the respiratory muscles are affected.
In case of overdose, treatment should be symptomatic. The tertiary anticholinergics, such as atropine, can be used as an antidote during an overdose of donepezil. Intravenous administration of atropine sulfate is recommended at the initial dose of 1.0 and 2.0 mg IV, to be renewed and adjusted if necessary according to clinical response. Atypical blood pressure and heart rate were observed with other cholinomimetics when co-administered with anticholinergic quaternary as glycopyrrolate. The dialysis elimination (hemodialysis, peritoneal dialysis or hemofiltration) of donepezil and / or its metabolites is not documented.
DELIVERY CONDITIONS:
List I, under medical prescription.
SPECIAL PRECAUTIONS OF STORAGE:
Store at a temperature not exceeding 30 ° C.
PRESENTATIONS AND M.A. NUMBERS:

Specialities	M.A.	Presentations
DOPEZIL 5 mg	923 350 1	Box of 30 coated tablets
DOPEZIL 10 mg	923 350 2	Box of 30 coated tablets

This is a drug
- A drug is a specific product agent.
- A drug is a product acting on your health and its use, contrary to prescriptions may be dangerous for you.
- Strictly respect the doctor's prescription and the instructions of use he has prescribed.
- Follow your pharmacist's kmow this drug ; its indiations and contra-indications.
- Do not discontinue the drug intake by yourself during the prescription period.
- Do not repeat the prescription or increase the dosage without consulting your doctor.

KEEP ANY DRUG OUT OF THE REACH OF CHILDREN.

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