xxxxxxxx-5343

# DONEPEZIL HCl

## TORPEZIL 5 / TORPEZIL 10

**5 mg and 10 mg Film-Coated Tablet**
**Acetylcholinesterase Inhibitor**

**FORMULATION:**
Each film-coated tablet contains:
Donepezil Hydrochloride, USP ..... 5 mg and 10 mg

**PRODUCT DESCRIPTION**
Donepezil Hydrochloride (Torpezil 5) 5 mg Film-Coated Tablet is a white to off white, circular, biconvex, film coated tablet, debossed with '5' on one side and breakline on other side.
Donepezil Hydrochloride (Torpezil 10) 10 mg Film-Coated Tablet is a peach colored, circular, biconvex, film coated tablet, debossed with '10' on one side and breakline on other side.

**PHARMACOKINETICS:**
Donepezil Hydrochloride is well absorbed from the gastrointestinal tract, maximum plasma concentrations being achieved within 3 to 4 hours. It is about 95% bound to plasma proteins. Donepezil undergoes partial metabolism via the cytochrome P450 system to major metabolites. About 11% of the dose is present in plasma as 6-O-desmethyl donepezil, which has similar activity to parent compound. Over 10 days, about 57% of a dose is recovered from the urine as unchanged drug and metabolites, and about 15% from the feces; 28% remains uncovered suggesting accumulation. The elimination half-life is about 70 hours. Steady state concentrations are achieved within 3 weeks of the start of therapy.

**INDICATIONS:**
Donepezil hydrochloride is used for the treatment of mild to moderately severe dementia in Alzheimer's disease.

**DOSAGE AND METHOD OF ADMINISTRATION:**
Initial dose of 5 mg once daily in the evening and increased if necessary after 4 to 6 weeks to a maximum of 10 mg once daily.

**CONTRAINDICATIONS:**
Donepezil Hydrochloride is contraindicated in patients with gastrointestinal or urinary tract obstruction, it is not recommended in patients recovering from bladder or gastrointestinal surgery.

**PRECAUTIONS:**
Care is required in patients with history of asthma, obstructive pulmonary disease, Parkinson's disease, or epilepsy and in those at risk of developing peptic ulcer disease. Patients with cardiovascular conduction disorders such as sinus syndrome may be susceptible to the vagotonic effects of the anticholinesterase. May exacerbate extrapyramidal symptoms.

**ADVERSE EFFECTS:**
Adverse effects of Donepezil include nausea, vomiting, anorexia, diarrhea, fatigue and dizziness. Other common adverse effects include abdominal pain, dyspepsia, headache, somnolence, muscle cramps, insomnia, sweating, tremor, and syncope; upper- respiratory tract infections have been noted. Rare cases of angina, sinoatrial and atrioventricular blocks, bradycardia, peptic ulcers, gastrointestinal hemorrhage, extrapyramidal symptoms, and seizures have been observed. Psychiatric disturbances, including depression, hallucinations, agitation, aggressive behavior and confusion have also been reported. There is a potential of bladder outflow obstruction. Minor increases in plasma-creatinine kinase have also occurred with donepezil.
The use of anticholinesterase has been associated with weight loss. Female patients have been found to be more susceptible to nausea, vomiting, anorexia, and weight loss.

"For suspected adverse drug reaction, report to FDA: www.fda.gov.ph or to TORRENT: www.torrentpharma.com".
Patient to seek medical attention immediately at the first sign of any adverse drug reaction shall appear.

**OVERDOSAGE:**
Overdosage may result in "cholinergic crisis", characterized by both muscarinic and nicotinic effects. These effects may include excessive sweating, lacrimation, increased peristalsis, involuntary defecation and urination or desire to urinate, miosis, ciliary spasm, nystagmus, bradycardia and other arrythmias, hypotension, muscle cramps, fasciculations, weakness, and paralysis, tight chest, wheezing and increased bronchial secretion combined with bronchoconstriction. Central Nervous System (CNS) effects includes ataxia, convulsions, coma, slurred speech, restlessness, agitation, and fear. Death may result from respiratory failure due to a combination of the muscarinic, nicotinic and central effects, or cardiac arrest.

**DRUG INTERACTIONS:**
Drugs with neuromuscular blocking activity such as the aminoglycosides, clindamycin, colistin, cyclopropane, and the halogenated inhalational anesthetics, may antagonize the effects of donepezil. A number of drugs including quinine, chloroquine, hydroxychloroquine, quinidine, procainamide, propafenone, lithium, and the beta blockers, that have a potential to aggravate myasthenia gravis can reduce the effectiveness of treatment with parasympathomimetics. Prolonged bradycardia has also occurred in patients receiving beta blockers when given with donepezil. Donepezil can inhibit the metabolism of suxamethonium and enhance and prolong its action.
Hepatic metabolism of donepezil via the cytochrome P450 system has been demonstrated; plasma concentrations of donepezil may be raised by drugs that inhibit the isoenzyme CYP3A4 such as ketoconazole, itraconazole, and erythromycin and by those that inhibit the isoenzyme CYP2D6 such as flouxetine and quinidine. Plasma concentrations may be reduced by enzyme inducers such as rifampicin, phenytoin, carbamazepine, and alcohol.

**CAUTION:**
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

**STORAGE:**
Store at temperatures not exceeding 30°C.

**AVAILABILITY**
Donepezil Hydrochloride (Torpezil 5) 5 mg Film-Coated Tablet - Alu-Alu Blister pack of 10's (Box of 100's) - DRP-3262
Donepezil Hydrochloride (Torpezil 10) 10 mg Film-Coated Tablet - Alu-Alu Blister pack of 10's (Box of 100's) - DRP-3263

**DATE OF FIRST AUTHORIZATION**
September 24, 2010

**DATE OF REVISION**
May 2016

torrent PHARMA

Manufactured by :
TORRENT PHARMACEUTICALS LTD.
Indrad-382 721, Dist. Mehsana, INDIA.

Imported and Distributed by :
**TORRENT PHARMA PHILIPPINES INC.**
Units 3 & 4, 34th Floor, Zuellig Building
Makati Avenue Corner Paseo de Roxas
Makati City, PHILIPPINES

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|---|---|---|---|---|---|---|---|---|---|
| **PRODUCT NAME** | : | Torpezil | **COUNTRY :** Philippines | **LOCATION :** Chhatral | **Supersedes A/W No.:** | | | | |
| **ITEM / PACK** | : | Insert | **NO. OF COLORS:** 1 | **REMARK :** | | | | | |
| **DESIGN STYLE** | : | Front-Back | **PANTONE SHADE NOS.:** | **SUBSTRATE :** | | | | | |
| **CODE** | : | xxxxxxxx-5343 | Black | **Activities** | **Department** | **Name** | **Signature** | **Date** | |
| **DIMENSIONS (MM)** | : | 150 x 250 | | Prepared By | **Pkg.Dev** | | | | |
| **ART WORK SIZE** | : | S/S | | Reviewed By | **Pkg.Dev** | | | | |
| **DATE** | : | 17-06-2016 | | Approved By | **Quality** | | | | |

**This colour proof is not colour binding. Follow Pantone shade reference for actual colour matching.**