

TORPEZIL TABLETS

Consumer Medication Information Leaflet (RiMUP)

Donepezil Hydrochloride Tablets U.S.P. 5mg, 10mg

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What Torpezil is used for?

Torpezil contains Donepezil hydrochloride. It is used to treat the symptoms of dementia in people diagnosed as having mild and moderately severe Alzheimer's disease. The symptoms include increasing memory loss, confusion and behavioral changes. As a result, sufferers of Alzheimer's disease find it more and more difficult to carry out their normal daily activities.

How Torpezil works

Donepezil hydrochloride belongs to a group of medicines called acetylcholinesterase inhibitors. Donepezil increases the levels of a substance (acetylcholine) in the brain involved in memory function by slowing down the break down of acetylcholine.

Before you use Torpezil

When you must not use it

- if you are allergic (hypersensitive) to donepezil hydrochloride, or to piperidine derivatives, or any of the other ingredients of Torpezil.

Before you start to use it

Tell your doctor or pharmacist before starting to take Torpezil if you have or have had:

- stomach or duodenal ulcers

- seizures (fits) or convulsions
- a heart condition (irregular or very slow heart beat)
- asthma or other long term lung disease
- liver problems or hepatitis
- difficulty passing urine or mild kidney disease

Also tell your doctor if you are pregnant or think you might be pregnant.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any of the following types of medicines:

- other Alzheimer's disease medicines, e.g. galantamine
- pain killers or treatment for arthritis e.g. aspirin, non-steroidal anti-inflammatory (NSAID) drugs such as ibuprofen, or diclofenac sodium
- anticholinergics medicines, e.g. tolterodine
- antibiotics e.g. erythromycin, rifampicin
- anti-fungal medicine e.g. ketoconazole
- anti-depressants e.g. fluoxetine
- anticonvulsants e.g. phenytoin, carbamazepine
- medication for a heart condition e.g. quinidine, beta-blockers (propranolol and atenolol)
- muscle relaxants e.g. diazepam, succinylcholine
- general anaesthetic
- medicines obtained without a prescription e.g. herbal remedies

If you are going to have an operation that requires you to have a general anaesthetic, you should tell your doctor and the anaesthetist that you are taking Torpezil. This is because your medicine may affect the amount of anaesthetic needed. Torpezil can be used in patients with kidney disease or mild to moderate liver disease. Tell your doctor first if you have kidney or liver disease. Patients with severe liver disease should not take Torpezil. Tell your doctor or pharmacist the name of your caregiver. Your caregiver will help

you to take your medicine as it is prescribed.

How to use Torpezil

How much to use

Usually, you will start by taking 5 mg every night. After one month, your doctor may tell you to take 10 mg every night. Swallow your Torpezil tablet with a drink of water before you go to bed at night. 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. The maximum recommended dose is 10 mg each night. Always follow your doctor's, or pharmacist's advice about how and when to take your medicine. Do not alter the dose yourself without your doctor's advice.

When to use it

Swallow your Torpezil tablet with a drink of water before you go to bed at night. You may take your tablets with or without food.

How long to use it

Your doctor or pharmacist will advise you on how long you should continue to take your tablets. You will need to see your doctor from time to time to review your treatment and assess your symptoms.

If you forget to use it

If you forget to take a tablet, just take one tablet the following day at the usual time. Do not take a double dose to make up for a forgotten tablet. If you forget to take your medicine for more than one week, call your doctor before taking any more medicine.

If you use too much (overdose)

Do not take more than one tablet each day. Call your doctor immediately if you take more than you should. If you cannot contact your doctor, contact the local hospital Accident and Emergency department at once. Always take the tablets and the carton with you to the

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hospital so that the doctor knows what has been taken. Symptoms of overdosing include feeling and being sick, drooling, sweating, slow heart rate, low blood pressure (light-headedness or dizziness when standing), breathing problems, losing consciousness and seizures (fits) or convulsions

While you are using Torpezil

Things you must do

Tell your doctor if

- you are, you think you might be or are planning to become pregnant.
 - you are breast-feeding or if you are planning to breast-feed your baby.
- Your doctor will advise you to discontinue this medicine.

Tell your doctor or pharmacist the name of your caregiver. Your caregiver will help you to take your medicine as it is prescribed.

Things you must not do

Alzheimer's disease may impair your ability to drive or operate machinery and you must not perform these activities unless your doctor tells you that it is safe to do so.

Also, your medicine can cause tiredness, dizziness and muscle cramp. If you experience any of these effects you must not drive or operate machinery.

Do not stop taking the tablets unless told to do so by your doctor. If you stop taking Torpezil, the benefits of your treatment will gradually fade away.

Things to be careful of

if you have or have had:

- stomach or duodenal ulcers
- seizures (fits) or convulsions
- a heart condition (irregular or very slow heart beat)
- asthma or other long term lung disease
- liver problems or hepatitis
- difficulty passing urine or mild kidney disease

Side effects

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

The following side effects have been reported by people taking Torpezil. Tell your doctor if you have any of these effects while you are taking Torpezil.

Most adverse events are mild in severity and transient in nature. The most common were diarrhea and muscle cramps. Other side effects are fatigue, nausea, vomiting, insomnia, and dizziness. There have been reports of psychiatric disturbances, including hallucinations, agitation and aggressive behavior which were resolved on dose reduction or discontinuation of treatment.

Treatment can be associated with minor increases in muscle creatine kinase blood concentrations. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting)

Storage and Disposal of Torpezil

Storage

- Store below 30° C.
- Keep medicines out of reach of children

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?

TORPEZIL 5 MG

White to off-white, Circular, biconvex film coated tablets debossed with '5' on one side and break line on other side.

TORPEZIL 10 MG

Peach coloured, circular, biconvex, film coated tablets debossed with '10' on one side and break line on other side.

Ingredients

Donepezil Hydrochloride
Starch (Maize starch)
Lactose and MCC (3:1)
Magnesium Stearate
Hypromellose 2910 (6 cps)
Polyethylene glycol 6000 (Macrogol)
Talc
Titanium Dioxide
Purified water
Ferric Oxide Yellow
Ferric Oxide Red

MAL number:

Torpezil Tablets 5 mg:

MAL13015046A

Torpezil Tablets 10 mg:

MAL13015045A

Manufacturer



TORRENT PHARMACEUTICALS LTD.

Indrad 382 721, District: Mehsana
INDIA.

Product Registration Holder

Laboratories Torrent (Malaysia) Sdn
Bhd.

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Date of Revision

28/05/2013