

TONIZEP ORALLY DISINTEGRATING TABLET 5/10 MG

Donepezil hydrochloride (5 mg and 10mg)

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What *Tonizep ODT* is used for

Tonizep ODT is a prescription medicine to treat dementia in Alzheimer's disease. The symptoms include increasing memory loss, confusion, and behavioural changes. As a result, sufferers of Alzheimer's disease find it more and more difficult to carry out their normal daily activities.

How *Tonizep ODT* works

Tonizep ODT will not cure this disease, but should help your memory and improve your ability to think more clearly. This medicine belongs to a group of medicines called acetylcholinesterase inhibitors. They are thought to work by increasing the levels of a substance (acetylcholine) in the brain involved in memory function by slowing down the breakdown of acetylcholine.

Tonizep ODT has not been approved as a treatment for any medical condition in children.

Before you use *Tonizep ODT*

- When you must not use it

Do not use *Tonizep ODT* if:

- you are phenylketonurics
- you are allergic to donepezil hydrochloride or any ingredients in *Tonizep ODT* or to medicines that contain piperidines.
- you are pregnant or breastfeeding, think you may be pregnant, or planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Tell the doctor about all your present or past health problems. Including:

- any heart problems including problems with irregular, slow, or fast heartbeats
- 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 has 'prolonged QT interval'
- low levels of magnesium or potassium in your blood
- asthma or lung problems
- other types of memory impairment
- any movement difficulties such as muscle stiffness or uncontrolled movements
- seizure or convulsions
- stomach or intestinal ulcers
- difficulty passing urine
- liver problems

- Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription. Be particularly sure to tell doctor if you are taking any of the following types of medicines:

- medicines for heart rhythm problems e.g. amiodarone, sotalol and quinidine
- medicines for depression e.g. citalopram, escitalopram, amitriptyline
- medicines for psychosis e.g. pimozide, sertindole, ziprasidone
- medicines for bacterial infections e.g. clarithromycin, erythromycin, levofloxacin, moxifloxacin
- pain killers e.g., nonsteroidal anti-inflammatory drugs (NSAIDs).
- antifungal e.g., ketoconazole, itraconazole
- anticonvulsants e.g., phenytoin, carbamazepine
- muscle relaxant e.g., succinylcholine

How to use *Tonizep ODT*

- How much to use

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. Treatment is initiated at 5mg/day (once-a-day dosing). 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

Tonizep ODT should be taken orally in the evening prior to retiring to bed. The tablet should be placed on the tongue and allowed to disintegrate before swallowing with or without water, according to your preference.

- How long to use it

Continue taking *Tonizep ODT* for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Overdose symptoms may include feeling and being sick, drooling, sweating, slow heart rate, low blood pressure, breathing problems, losing consciousness and seizures or convulsions.

While you are using it

- Things you must do

- Tell all the doctors, dentists and pharmacists treating you that you are taking *Tonizep ODT*
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking your medicines unless advised by your doctor.
- Do not use *Tonizep ODT* after the expiry date which is stated on the carton and tube.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give this medication to anyone else, even if they have the same condition as you.

- Things to be careful of

Dementia may cause impairment of driving performance or compromise the abil-

ity to use machinery. Check with your doctor or pharmacist.

Tonizep ODT should not be taken with alcohol. Also, your medicine can cause tiredness, dizziness, and muscle cramp, mainly when initiating or increasing the dose. If you experience any of these effects, you must not drive or operate machinery.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Tonizep ODT may cause the following serious side effects:

- slow heartbeat and fainting. This happens more often in people with heart problems. Call the doctor right away if you faint while taking *Tonizep ODT*
- more stomach acid. This raises the chance of ulcers and bleeding, especially when taking *Tonizep ODT*. The risk is higher for people who had ulcers, or other NSAIDs
- liver damage e.g., hepatitis
- seizures
- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called “Neuroleptic Malignant Syndrome”)

The most common side effects are:

- nausea
- diarrhoea
- difficulty in sleeping
- vomiting
- muscle cramps
- feeling tired
- loss of appetite
- headache
- hallucinations (hear, smell, taste or feel things that do not exist)
- common cold
- rash
- abnormal dreams and nightmares
- abdominal disturbances
- itching
- aggressive behaviour
- pass urine uncontrollably
- agitation
- dizziness

Unknown (frequency cannot be estimated):

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccine (AEFI)].

Storage and Disposal of *Tonizep ODT*

Storage

Store in tight containers at temperature below 30 °C.

Tablet may change colour with light, so keep in aluminium pouch until taken. Keep 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

Tonizep Orally Disintegrating Tablet 5mg: White, round tablets embossed with “5” on one side and “ZD” on another.

Tonizep Orally Disintegrating Tablet 10mg: Yellow, round tablet embossed with “10” on one side and “ZD” on another side.

- Ingredients

- Active ingredient: Donepezil Hydrochloride
- Inactive ingredients: Corn starch, mannitol powder, spray dried mannitol, colloidal silicon dioxide, aspartame, crospovidone, sodium stearyl fumarate. Additionally, the 10mg tablet contains yellow ferric oxide.

- MAL Number

Tonizep Orally Disintegrating Tablet 5mg: MAL21056017AZ

Tonizep Orally Disintegrating Tablet 10mg: MAL23096024AZ

Manufacturer

T.O. Chemicals (1979) Ltd.
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Product Registration Holder

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